ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

▼ This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions. See section 4.8 for how to report adverse reactions.

1. NAME OF THE MEDICINAL PRODUCT

Sondelbay 20 micrograms/80 microliters solution for injection in pre-filled pen

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose contains 20 micrograms of teriparatide* in 80 microliters.
One pre-filled pen of 2.4 mL contains 600 micrograms of teriparatide. Each millilitre of the solution for injection contains 250 micrograms of teriparatide.

*Teriparatide, rhPTH(1-34), produced in *Escherichia. coli*, using recombinant DNA technology, is identical to the 34 N-terminal amino acid sequence of endogenous human parathyroid hormone.

For the full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Solution for injection (injection).

Colourless, clear solution.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Sondelbay is indicated in adults.

Treatment of osteoporosis in postmenopausal women and in men at increased risk of fracture (see section 5.1). In postmenopausal women, a significant reduction in the incidence of vertebral and non-vertebral fractures but not hip fractures have been demonstrated.

Treatment of osteoporosis associated with sustained systemic glucocorticoid therapy in women and men at increased risk for fracture (see section 5.1).

4.2 Posology and method of administration

Posology

The recommended dose of Sondelbay is 20 micrograms administered once daily.

The maximum total duration of treatment with Sondelbay should be 24 months (see section 4.4). The 24-month course of Sondelbay should not be repeated over a patient's lifetime.

Patients should receive supplemental calcium and vitamin D supplements if dietary intake is inadequate.

Following cessation of Sondelbay therapy, patients may be continued on other osteoporosis therapies.

Special populations

Elderly
Dose adjustment based on age is not required (see section 5.2).

Renal impairment
Sondelbay must not be used in patients with severe renal impairment (see section 4.3.). In patients with moderate renal impairment, Sondelbay should be used with caution. No special caution is required for patients with mild renal impairment.

Hepatic impairment
No data are available in patients with impaired hepatic function (see section 5.3). Therefore, Sondelbay should be used with caution.

Paediatric population and young adults with open epiphyses
The safety and efficacy of teriparatide in children and adolescents less than 18 years has not been established. Sondelbay should not be used in paediatric patients (less than 18 years), or young adults with open epiphyses.

Method of administration

Sondelbay should be administered once daily by subcutaneous injection in the thigh or abdomen.

Patients must be trained to use the proper injection techniques For instructions of the medicinal product before administration (see section 6.6). A user manual is also available to instruct patients on the correct use of the pen.

4.3 Contraindications

- Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.
- Pregnancy and breast-feeding (see sections 4.4 and 4.6)
- Pre-existing hypercalcaemia
- Severe renal impairment
- Metabolic bone diseases (including hyperparathyroidism and Paget's disease of the bone) other than primary osteoporosis or glucorticoid-induced osteoporosis.
- Unexplained elevations of alkaline phosphatase
- Prior external beam or implant radiation therapy to the skeleton
- Patients with skeletal malignancies or bone metastases should be excluded from treatment with teriparatide.

4.4 Special warnings and precautions for use

Traceability

In order to improve the traceability of biological medicinal products, the name and the batch number of the administered product should be clearly recorded.

Serum and urine calcium

In normocalcaemic patients, slight and transient elevations of serum calcium concentrations have been observed following teriparatide injection. Serum calcium concentrations reach a maximum between 4 and 6 hours and return to baseline by 16 to 24 hours after each dose of teriparatide. Therefore, if blood samples for serum calcium measurements are taken, this should be done at least 16 hours after the most recent teriparatide injection. Routine calcium monitoring during therapy is not required.

Teriparatide may cause small increases in urinary calcium excretion, but the incidence of hypercalciuria did not differ from that in the placebo-treated patients in clinical trials.

Urolithiasis

Teriparatide has not been studied in patients with active urolithiasis. Sondelbay should be used with caution in patients with active or recent urolithiasis because of the potential to exacerbate this condition.

Orthostatic hypotension

In short-term clinical trials with teriparatide, isolated episodes of transient orthostatic hypotension were observed. Typically, an event began within 4 hours of dosing and spontaneously resolved within a few minutes to a few hours. When transient orthostatic hypotension occurred, it happened within the first several doses, was relieved by placing subjects in a reclining position, and did not preclude continued treatment.

Renal impairment

Caution should be exercised in patients with moderate renal impairment.

Younger adult population

Experience in the younger adult population (>18 to 29 years), including premenopausal women, is limited (see section 5.1). Treatment should only be initiated if the benefit clearly outweighs risks in this population.

Women of childbearing potential should use effective methods of contraception during use of teriparatide.. If pregnancy occurs, Sondelbay should be discontinued.

Duration of treatment

Studies in rats indicate an increased incidence of osteosarcoma with long-term administration of teriparatide (see section 5.3). Until further clinical data become available, the recommended treatment time of 24 months should not be exceeded.

Excipient

This medicinal product contains less than 1 mmol sodium (23 mg) per dose unit, that is to say essentially ‘sodium-free’.

4.5 Interaction with other medicinal products and other forms of interaction

In a study of 15 healthy subjects administered digoxin daily to steady state, a single teriparatide dose did not alter the cardiac effect of digoxin. However, sporadic case reports have suggested that hypercalcaemia may predispose patients to digitalis toxicity. Because teriparatide transiently increases serum calcium, teriparatide should be used with caution in patients taking digitalis.

Teriparatide has been evaluated in pharmacodynamic interaction studies with hydrochlorothiazide. No clinically significant interactions were noted.

Co-administration of raloxifene or hormone replacement therapy with teriparatide did not alter the effects of teriparatide on serum or urine calcium or on clinical adverse events.

4.6 Fertility, pregnancy and lactation

Women of childbearing potential / Contraception in females

Women of childbearing potential should use effective methods of contraception during use of teriparatide. If pregnancy occurs, Sondelbay should be discontinued.

Pregnancy

Sondelbay is contraindicated for use during pregnancy (see section 4.3).

Breast-feeding

Sondelbay is contraindicated for use during breast-feeding. It is not known whether teriparatide is excreted in human milk.

Fertility

Studies in rabbits have shown reproductive toxicity (see section 5.3). The effect of teriparatide on human foetal development has not been studied. The potential risk for humans is unknown.

4.7 Effects on ability to drive and use machines

Teriparatide has no or negligible influence on the ability to drive and use machines. Transient, orthostatic hypotension or dizziness was observed in some patients. These patients should refrain from driving or the use of machines until symptoms have subsided.

4.8 Undesirable effects

Summary of the safety profile

The most commonly reported adverse reactions in patients treated with teriparatide are nausea, pain in limb, headache and dizziness.

Tabulated list of adverse reactions

Of patients in the teriparatide trials, 82.8 % of the teriparatide patients and 84.5 % of the placebo patients reported at least 1 adverse event.

The adverse reactions associated with the use of teriparatide in osteoporosis clinical trials and post-marketing exposure are summarised in the table below. The following convention has been used for the classification of the adverse reactions: very common (≥ 1/10), common (≥ 1/100 to <1/10), uncommon (≥ 1/1,000 to <1/100), rare (≥ 1/10,000 to <1/1,000) very rare (<1/10,000).

Table 1. Adverse drug reactions

Organ class system	**Very common**	**Common**	**Uncommon**	**Rare**
Blood and lymphatic system disorders		Anaemia		
Immune system disorders				Anaphylaxis
Metabolism and nutrition		Hypercholesterolaemia	Hypercalcaemia greater than	Hypercalcaemia greater than

disorders			2.76 mmol/L, hyperuricemia	3.25 mmol/L
Psychiatric disorders		Depression		
Nervous system disorders		Dizziness, headache, sciatica, syncope		
Ear and labyrinth disorders		Vertigo		
Cardiac disorders		Palpitations	Tachycardia	
Vascular disorders		Hypotension		
Respiratory, thoracic and mediastinal disorders		Dyspnoea	Emphysema	
Gastrointestinal disorders		Nausea, vomiting, hiatus hernia, gastro-oesophageal reflux disease	Haemorrhoids	
Skin and subcutaneous tissue disorders		Sweating Increased		
Musculoskeletal and connective tissue disorders	Pain in limb	Muscle cramps	Myalgia, arthralgia, back cramp/pain*	
Renal and urinary disorders			Urinary incontinence, polyuria, micturition urgency, nephrolithiasis	Renal failure/impairment
General disorders and administration site condition		Fatigue, chest pain, asthenia, mild and transient injection site events, including pain, swelling, erythema, localised bruising, pruritus and minor bleeding at injection site	Injection site erythema, injection site reaction	Possible allergic events soon after injection: acute dyspnoea, oro/facial oedema, generalised urticaria, chest pain, oedema (mainly peripheral)
Investigations			Weight increased, cardiac murmur, alkaline phosphatase increase	

*Serious cases of back cramp or pain have been reported within minutes of the injection.

Description of selected adverse reactions

In clinical trials the following reactions were reported at a ≥ 1 % difference in frequency from placebo: vertigo, nausea, pain in limb, dizziness, depression, dyspnoea.

Teriparatide increases serum uric acid concentrations. In clinical trials, 2.8 % of teriparatide patients had serum uric acid concentrations above the upper limit of normal compared with 0.7 % of placebo patients. However, the hyperuricemia did not result in an increase in gout, arthralgia, or urolithiasis.

In a large clinical trial, for another teriparatide product antibodies that cross-reacted with that teriparatide product were detected in 2.8 % of women. Generally, antibodies were first detected following 12 months of treatment and diminished after withdrawal of therapy. There was no evidence of hypersensitivity reactions, allergic reactions, effects on serum calcium, or effects on Bone Mineral Density (BMD) response.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the national reporting system listed in Appendix V.

4.9 Overdose

Signs and symptoms

Teriparatide has been administered in single doses of up to 100 micrograms and in repeated doses of up to 60 micrograms/day for 6 weeks.

The effects of overdose that might be expected include delayed hypercalcaemia and risk of orthostatic hypotension. Nausea, vomiting, dizziness, and headache can also occur.

Overdose experience based on post-marketing spontaneous reports

In post-marketing spontaneous reports, there have been cases of medication error where the entire contents (up to 800 micrograms) of the teriparatide pen have been administered as a single dose. Transient events reported have included nausea, weakness/lethargy and hypotension. In some cases, no adverse events occurred as a result of the overdose. No fatalities associated with overdose have been reported.

Overdose management

There is no specific antidote for teriparatide. Treatment of suspected overdose should include transitory discontinuation of teriparatide, monitoring of serum calcium, and implementation of appropriate supportive measures, such as hydration.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Calcium homeostasis, parathyroid hormones and analogues, ATC code: H05AA02.

Sondelbay is a biosimilar medicinal product. Detailed information is available on the website of the European Medicines Agency http://www.ema.europa.eu.

Mechanism of action

Endogenous 84-amino-acid parathyroid hormone (PTH) is the primary regulator of calcium and phosphate metabolism in bone and kidney. Teriparatide (rhPTH(1-34)) is the active fragment (1-34) of endogenous human parathyroid hormone. Physiological actions of PTH include stimulation of bone formation by direct effects on bone forming cells (osteoblasts) indirectly increasing the intestinal absorption of calcium and increasing the tubular re-absorption of calcium and excretion of phosphate by the kidney.

Pharmacodynamic effects

Teriparatide is a bone formation agent to treat osteoporosis. The skeletal effects of teriparatide depend upon the pattern of systemic exposure. Once-daily administration of teriparatide increases apposition of new bone on trabecular and cortical bone surfaces by preferential stimulation of osteoblastic activity over osteoclastic activity.

Clinical efficacy

Risk factors
Independent risk factors, for example, low BMD, age, the existence of previous fracture, family history of hip fractures, high bone turnover and low body mass index should be considered in order to identify women and men at increased risk of osteoporotic fractures who could benefit from treatment.

Premenopausal women with glucocorticoid-induced osteoporosis should be considered at high risk for fracture if they have a prevalent fracture or a combination of risk factors that place them at high risk for fracture (e.g., low bone density [e.g., T score ≤−2], sustained high dose glucocorticoid therapy [e.g., ≥7.5 mg/day for at least 6 months], high underlying disease activity, low sex steroid levels).

Postmenopausal osteoporosis
The pivotal trial included 1,637 postmenopausal women (mean age 69.5 years). At baseline, ninety percent of the patients had one or more vertebral fractures, and on average, vertebral BMD was 0.82 g/cm^2 (equivalent to a T-score = - 2.6). All patients were offered 1,000 mg calcium per day and at least 400 IU vitamin D per day. Results from up to 24 months (median: 19 months) treatment with teriparatide demonstrate statistically significant fracture reduction (Table 2). To prevent one or more new vertebral fractures, 11 women had to be treated for a median of 19 months.

Table 2. Fracture incidence in postmenopausal women

	Placebo (N = 544) (%)	Teriparatide (N= 541) (%)	Relative risk (95% CI) vs. placebo
New vertebral fracture (≥1)[a]	14.3	5.0[b]	0.35 (0.22, 0.55)
Multiple vertebral fractures (≥2)[a]	4.9	1.1[b]	0.23 (0.09, 0.60)
Non-vertebral fragility fractures[c]	5.5	2.6[d]	0.47 (0.25, 0.87)
Major non-vertebral fragility fractures[c] (hip, radius, humerus, ribs and pelvis)	3.9	1.5[d]	0.38 (0.17, 0.86)

Abbreviations: N = number of patients randomly assigned to each treatment group; CI = Confidence Interval.

[a] The incidence of vertebral fractures was assessed in 448 placebo and 444 Teriparatide patients who had baseline and follow-up spine radiographs.
[b] p≤0.001 compared with placebo
[c] A significant reduction in the incidence of hip fractures has not been demonstrated
[d] p≤0.025 compared with placebo.

After 19 months (median) treatment, (BMD) had increased in the lumbar spine and total hip, respectively, by 9 % and 4 % compared with placebo ($p<0.001$).

Post-treatment management: Following treatment with teriparatide, 1,262 postmenopausal women from the pivotal trial enrolled in a post-treatment follow-up trial. The primary objective of the trial was to collect safety data of teriparatide. During this observational period, other osteoporosis treatments were allowed and additional assessment of vertebral fractures was performed.

During a median of 18 months following discontinuation of teriparatide, there was a 41 % reduction ($p=0.004$) compared with placebo in the number of patients with a minimum of one new vertebral fracture.

In an open-label trial, 503 postmenopausal women with severe osteoporosis and a fragility fracture within the previous 3 years (83 % had received previous osteoporosis therapy) were treated with teriparatide for up to 24 months. At 24 months, the mean increase from baseline in lumbar spine, total hip and femoral neck BMD was 10.5 %, 2.6 % and 3.9 % respectively. The mean increase in BMD from 18 to 24 months was 1.4 %, 1.2 %, and 1.6 % at the lumbar spine, total hip and femoral neck, respectively.

A 24-month, randomised, double-blind, comparator-controlled phase 4 trial included 1,360 postmenopausal women with established osteoporosis. 680 subjects were randomised to teriparatide and 680 subjects were randomised to oral risedronate 35 mg/week. At baseline, the women had a mean age of 72.1 years and a median of 2 prevalent vertebral fractures; 57.9% of patients had received previous bisphosphonate therapy and 18.8% took concomitant glucocorticoids during the trial. 1,013 (74.5%) patients completed the 24-month follow-up. The mean (median) cumulative dose of glucocorticoid was 474.3 (66.2) mg in the teriparatide arm and 898.0 (100.0) mg in the risedronate arm. The mean (median) vitamin D intake for the teriparatide arm was 1433 IU/day (1400 IU/day) and for the risedronate arm was 1191 IU/day (900 IU/day). For those subjects who had baseline and follow-up spine radiographs, the incidence of new vertebral fractures was 28/516 (5.4%) in teriparatide- and 64/533 (12.0%) in risedronate-treated patients, relative risk (95% CI) = 0.44 (0.29-0.68), $P<0.0001$. The cumulative incidence of pooled clinical fractures (clinical vertebral and non vertebral fractures) was 4.8% in teriparatide and 9.8% in risedronate-treated patients, hazard ratio (95% CI) = 0.48 (0.32-0.74), $P=0.0009$.

Male osteoporosis
437 patients (mean age 58.7 years) were enrolled in a clinical trial for men with hypogonadal (defined as low morning free testosterone or an elevated FSH or LH) or idiopathic osteoporosis. Baseline spinal and femoral neck bone mineral density mean T-scores were -2.2 and -2.1, respectively. At baseline, 35 % of patients had a vertebral fracture and 59 % had a non-vertebral fracture.

All patients were offered 1000 mg calcium per day and at least 400 IU vitamin D per day. Lumbar spine BMD significantly increased by 3 months. After 12 months, BMD had increased in the lumbar spine and total hip by 5 % and 1 %, respectively, compared with placebo**.** However, no significant effect on fracture rates was demonstrated.

Glucocorticoid-induced osteoporosis
The efficacy of teriparatide in men and women (N=428) receiving sustained systemic glucocorticoid therapy (equivalent to 5 mg or greater of prednisone for at least 3 months) was demonstrated in the 18-month primary phase of a 36 month, randomised, double-blind, comparator-controlled trial (alendronate 10 mg/day). Twenty-eight percent of patients had one or more radiographic vertebral fractures at baseline. All patients were offered 1,000 mg calcium per day and 800 IU vitamin D per day.

This trial included postmenopausal women (N=277), premenopausal women (N=67), and men (N=83). At baseline, the postmenopausal women had a mean age of 61 years, mean lumbar spine BMD T score of −2.7, median prednisone equivalent dose of 7.5 mg/day, and 34 % had one or more radiographic vertebral fractures; premenopausal women had a mean age of 37 years, mean lumbar

spine BMD T score of −2.5, median prednisone equivalent dose of 10 mg/day, and 9 % had one or more radiographic vertebral fractures; and men had a mean age of 57 years, mean lumbar spine BMD T score of −2.2, median prednisone equivalent dose of 10 mg/day, and 24 % had one or more radiographic vertebral fractures.

Sixty-nine percent of patients completed the 18-month primary phase. At the 18 month endpoint, teriparatide significantly increased lumbar spine BMD (7.2 %) compared with alendronate (3.4 %) ($p<0.001$). Teriparatide increased BMD at the total hip (3.6 %) compared with alendronate (2.2 %) ($p<0.01$), as well as at the femoral neck (3.7 %) compared with alendronate (2.1 %) ($p<0.05$). In patients treated with teriparatide, lumbar spine, total hip and femoral neck BMD increased between 18 and 24 months by an additional 1.7 %, 0.9 %, and 0.4 %, respectively.

At 36 months, analysis of spinal X-rays from 169 alendronate patients and 173 teriparatide patients showed that 13 patients in the alendronate group (7.7 %) had experienced a new vertebral fracture compared with 3 patients in the teriparatide group (1.7 %) ($p=0.01$). In addition, 15 of 214 patients in the alendronate group (7.0 %) had experienced a non-vertebral fracture compared with 16 of 214 patients in the teriparatide group (7.5 %) ($p=0.84$).

In premenopausal women, the increase in BMD from baseline to 18 month endpoint was significantly greater in the teriparatide group compared with the alendronate group at the lumbar spine (4.2 % versus −1.9 %; $p<0.001$) and total hip (3.8 % versus 0.9 %; $p=0.005$). However, no significant effect on fracture rates was demonstrated.

5.2 Pharmacokinetic properties

Distribution

The volume of distribution is approximately 1.7 L/kg. The half-life of teriparatide is approximately 1 hour when administered subcutaneously, which reflects the time required for absorption from the injection site.

Biotransformation

No metabolism or excretion studies have been performed with teriparatide, but the peripheral metabolism of parathyroid hormone is believed to occur predominantly in liver and kidney.

Elimination

Teriparatide is eliminated through hepatic and extra-hepatic clearance (approximately 62 L/hr in women and 94 L/hr in men).

Elderly

No differences in teriparatide pharmacokinetics were detected with regard to age (range 31 to 85 years). Dose adjustment based on age is not required.

5.3 Preclinical safety data

Teriparatide was not genotoxic in a standard battery of tests. It produced no teratogenic effects in rats, mice or rabbits. There were no important effects observed in pregnant rats or mice administered teriparatide at daily doses of 30 to 1,000 µg/kg. However, fetal resorption and reduced litter size occurred in pregnant rabbits administered daily doses of 3 to 100 µg/kg. The embryotoxicity observed in rabbits may be related to their much greater sensitivity to the effects of PTH on blood ionised calcium compared with rodents.

Rats treated with near-life time daily injections had dose-dependent exaggerated bone formation and increased incidence of osteosarcoma most probably due to an epigenetic mechanism. Teriparatide did

not increase the incidence of any other type of neoplasia in rats. Due to the differences in bone physiology in rats and humans, the clinical relevance of these findings is probably minor. No bone tumours were observed in ovariectomised monkeys treated for 18 months or during a 3-year follow-up period after treatment cessation. In addition, no osteosarcomas have been observed in clinical trials or during the post treatment follow-up study.

Animal studies have shown that severely reduced hepatic blood flow decreases exposure of PTH to the principal cleavage system (Kupffer cells) and consequently clearance of PTH(1-84).

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Glacial acetic acid
Sodium acetate (anhydrous)
Mannitol
Metacresol
Hydrochloric acid (for pH adjustment)
Sodium hydroxide (for pH adjustment)
Water for injections

6.2 Incompatibilities

In the absence of compatibility studies, this medicinal product must not be mixed with other medicinal products.

6.3 Shelf life

2 years

<u>After first opening</u>

Chemical, physical and microbiological in-use stability has been demonstrated for 28 days at 2-8°C.

Once opened, the product may be stored for a maximum of 28 days at 2-8°C (refrigerated condition) temperature. Other in-use storage times and conditions are the responsibility of the user.

The medicinal product can be stored at temperature conditions up to 25°C for a maximum of 3 days when refrigeration is not available, after which it should be returned to the refrigerator and used within 28 days of the first injection. The Sondelbay pen should be discarded, if it has been kept out of refrigerator up to 25°C for more than 3 days.

6.4 Special precautions for storage

Store in a refrigerator (2°C – 8°C). Do not freeze. Store in the original package in order to protect from light

For storage conditions after first opening of the medicinal product, see section 6.3

6.5 Nature and contents of container

2.4 mL solution in cartridge (siliconised Type I glass) with a plunger (bromobutyl rubber), disc seal (bromobutyl lined aluminium seals), assembled into a disposable pen.

Each pre-filled pen contains 28 doses of 20 micrograms (per 80 microliters).

Sondelbay is available in pack sizes of 1 or 3 pre-filled pens (without needles), and 1 pre-filled pen (with 28 disposable sterile needles, 32G; 4mm).
Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

Handling

Sondelbay is supplied in a pre-filled pen. Each pen should be used by only one patient. A new sterile needle must be used for every injection.

The pen can be used with needles of 31G or 32G and 4mm, 5mm or 8mm length.

Sondelbay should not be used if the solution is cloudy, coloured or contains particles.

Sondelbay pen should be returned to the refrigerator (2°C-8°C) immediately after use. Recap the pen when not in use to protect the cartridge from physical damage and light.
Do not use Sondelbay if it is, or has been, frozen.

Do not transfer the medicine into a syringe.

Do not store the pre-filled pen with the needle attached.

Date of the first injection should be written on the outer carton of Sondelbay (see the provided space: date of first use).
Please also refer to the user manual for instructions on how to use the pen.

Disposal

Any unused product or waste material should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Accord Healthcare S.L.U.
World Trade Centre, Moll de Barcelona s/n,
Edifici Est, 6ª Planta,
08039, Barcelona, Spain

8. MARKETING AUTHORISATION NUMBER

EU/1/22/1628/001
EU/1/22/1628/002
EU/1/22/1628/003

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 24 March 2022

10. DATE OF REVISION OF THE TEXT

Detailed information on this medicinal product is available on the website of the European Medicines Agency http://www.ema.europa.eu

ANNEX II

A. MANUFACTURER(S) OF THE BIOLOGICAL ACTIVE SUBSTANCE(S) AND MANUFACTURER(S) RESPONSIBLE FOR BATCH RELEASE

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

C. OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION

D. CONDITIONS OR RESTRICTIONS WITH REGARD TO THE SAFE AND EFFECTIVE USE OF THE MEDICINAL PRODUCT

A. MANUFACTURER(S) OF THE BIOLOGICAL ACTIVE SUBSTANCE(S) AND MANUFACTURER(S) RESPONSIBLE FOR BATCH RELEASE

Name and address of the manufacturer(s) of the biological active substance(s)

Intas Pharmaceuticals Ltd.
Plot no: 423/P/A
Sarkhej Bavla Highway
Village Moraiya; Taluka Sanand,
Ahmedabad – 382213 Gujarat
India

Name and address of the manufacturer(s) responsible for batch release

Accord Healthcare Polska Sp.z o.o.,
ul. Lutomierska 50,
95-200 Pabianice,
Poland

The printed package leaflet of the medicinal product must state the name and address of the manufacturer responsible for the release of the concerned batch.

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

Medicinal product subject to medical prescription.

C. OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION

- **Periodic safety update reports (PSURs)**

The requirements for submission of PSURs for this medicinal product are set out in the list of Union reference dates (EURD list) provided for under Article 107c(7) of Directive 2001/83/EC and any subsequent updates published on the European medicines web-portal.

D. CONDITIONS OR RESTRICTIONS WITH REGARD TO THE SAFE AND EFFECTIVE USE OF THE MEDICINAL PRODUCT

- **Risk management plan (RMP)**

The marketing authorisation holder (MAH) shall perform the required pharmacovigilance activities and interventions detailed in the agreed RMP presented in Module 1.8.2. of the marketing authorisation and any agreed subsequent updates of the RMP.

An updated RMP should be submitted:

- At the request of the European Medicines Agency;
- Whenever the risk management system is modified, especially as the result of new information being received that may lead to a significant change to the benefit/risk profile or as the result of an important (pharmacovigilance or risk minimisation) milestone being reached.

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

OUTER CARTON TEXT

1. NAME OF THE MEDICINAL PRODUCT

Sondelbay 20 micrograms/80 microliters solution for injection in pre-filled pen
teriparatide

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each dose contains 20 micrograms of teriparatide in 80 microliters.
One pre-filled pen of 2.4 mL contains 600 micrograms of teriparatide (corresponding to 250 micrograms per mL).

3. LIST OF EXCIPIENTS

Excipients: glacial acetic acid, sodium acetate (anhydrous), mannitol, metacresol, water for injection. Hydrochloric acid solution and/or sodium hydroxide solution (for pH adjustment).

See leaflet for further information.

4. PHARMACEUTICAL FORM AND CONTENTS

Solution for injection.

1 pre-filled pen
3 pre-filled pens
1 pre-filled pen + 28 needles

Each pre-filled pen contains 28 doses of 20 micrograms of teriparatide (per 80 microliters).

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.
Subcutaneous use

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

Keep out of the sight and reach of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

8. EXPIRY DATE

EXP

The pen should be discarded 28 days after the first use.
Date of first use: 1. ...../2. ...../3. .....{the grey-shaded text refers to the 3x pack size}

9. SPECIAL STORAGE CONDITIONS

Store in a refrigerator.
Do not freeze.
Store in the in the original package in order to protect from light.

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Accord Healthcare S.L.U.
World Trade Centre, Moll de Barcelona s/n,
Edifici Est, 6ª Planta,
Barcelona, 08039, Spain

12. MARKETING AUTHORISATION NUMBER(S)

EU/1/22/1628/001
EU/1/22/1628/002
EU/1/22/1628/003

13. BATCH NUMBER

Lot

14. GENERAL CLASSIFICATION FOR SUPPLY

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

Sondelbay

17. UNIQUE IDENTIFIER – 2D BARCODE

2D barcode carrying the unique identifier included.

18. UNIQUE IDENTIFIER - HUMAN READABLE DATA

PC
SN
NN

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

LABEL TEXT

1. NAME OF THE MEDICINAL PRODUCT AND ROUTE(S) OF ADMINISTRATION

Sondelbay 20 micrograms/80 microliters, injection
teriparatide
SC use

2. METHOD OF ADMINISTRATION

Subcutaneous use

3. EXPIRY DATE

EXP

4. BATCH NUMBER

Lot

5. CONTENTS BY WEIGHT, BY VOLUME OR BY UNIT

2.4 mL

6. OTHER

Number of doses

B. PACKAGE LEAFLET

Package leaflet: Information for the user

Sondelbay 20 micrograms/80 microliters solution for injection in pre-filled pen
teriparatide

▼This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Sondelbay is and what it is used for
2. What you need to know before you use Sondelbay
3. How to use Sondelbay
4. Possible side effects
5 How to store Sondelbay
6. Contents of the pack and other information

1. What Sondelbay is and what it is used for

Sondelbay contains the active substance teriparatide that is used to make the bones stronger, and to reduce the risk of fractures by stimulating bone formation.

Sondelbay is used to treat osteoporosis in adults. Osteoporosis is a disease that causes your bones to become thin and fragile. This disease is especially common in women after the menopause, but it can also occur in men. Osteoporosis is also common in patients receiving corticosteroids.

2. What you need to know before you use Sondelbay

Do not use Sondelbay
- if you are allergic to teriparatide or any of the other ingredients of this medicine (listed in section 6).
- if you suffer from high calcium levels (pre-existing hypercalcaemia).
- if you suffer from serious kidney problems.
- if you have ever been diagnosed with bone cancer or other cancers that have spread (metastasised) to your bones.
- if you have certain bone diseases. If you have a bone disease, tell your doctor.
- if you have unexplained high levels of alkaline phosphatase in your blood, which means you might have Paget's disease of bone (disease with abnormal bone changes). If you are not sure, ask your doctor.
- if you have had radiation therapy involving your bones.
- if you are pregnant or breast-feeding.

Warnings and precautions
Sondelbay may cause an increase in the amount of calcium in your blood or urine.

Talk to your doctor or pharmacist before or while using Sondelbay:

- if you have continuing nausea, vomiting, constipation, low energy, or muscle weakness. These may be signs there is too much calcium in your blood.
- if you suffer from kidney stones or have a history of kidney stones.
- if you suffer from kidney problems (moderate renal impairment).

Some patients get dizzy or get a fast heartbeat after the first few doses. For the first doses, inject Sondelbay where you can sit or lie down right away if you get dizzy.

The recommended treatment time of 24 months should not be exceeded.

Sondelbay should not be used in growing adults.

Children and adolescents
Sondelbay should not be used in children and adolescents (less than 18 years).

Other medicines and Sondelbay
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, because occasionally they may interact (e.g. digoxin/digitalis, a medicine used to treat heart disease).

Pregnancy and breast-feeding
Do not use Sondelbay if you are pregnant or breast-feeding. If you are a woman of child-bearing potential, you should use effective methods of contraception during use of Sondelbay. If you become pregnant, Sondelbay should be discontinued. Ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines
Some patients may feel dizzy after injecting Sondelbay. If you feel dizzy you should not drive or use machines until you feel better.

Sondelbay contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially "sodium-free".

3. How to use Sondelbay

Always use this medicine exactly as your doctor has told you to. Check with your doctor or pharmacist if you are not sure.

The recommended dose is 20 micrograms (in 80 microliters) given once daily by injection under the skin (subcutaneous injection) in the thigh or abdomen. To help you remember to use your medicine, inject it at about the same time each day.

Inject Sondelbay each day for as long as your doctor prescribes it for you. The total duration of treatment with Sondelbay should not exceed 24 months. You should not receive more than one treatment course of 24 months over your lifetime.

Read the instructions for use, on how to use the Sondelbay pen.

Sondelbay is available in packs of 1 or 3 pens without needles. Sondelbay can be used with pen needles (31G or 32G; 4 mm, 5 mm or 8 mm).

Sondelbay is also available in packs of 1 pen with 28 disposable sterile needles (32G; 4 mm).

You should use your Sondelbay injection shortly after you take the pen out of the refrigeratoras described in the user manual. Put the pen back into the refrigerator immediately after you have used it. Use a new injection needle for each injection and dispose of it after each use. Never store your pen with the needle attached. Never share your Sondelbay pen with others.

Your doctor may advise you to use Sondelbay with calcium and vitamin D. Your doctor will tell you how much you should take each day.

Sondelbay can be given with or without food.

If you use more Sondelbay than you should
If, by mistake, you have used more Sondelbay than you should, contact your doctor or pharmacist.

The effects of overdose that might be expected include nausea, vomiting, dizziness, and headache.

If you forget or cannot use Sondelbay at your usual time, use it as soon as possible on that day. Do not use a double dose to make up for a forgotten dose. Do not use more than one injection in the same day. Do not try to make up for a missed dose.

If you stop using Sondelbay
If you are considering stopping Sondelbay treatment, please discuss this with your doctor. Your doctor will advise you and decide how long you should be treated with Sondelbay.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

The most common side effects are pain in limb (frequency is very common, may affect more than 1 in 10 people) and feeling sick, headache and dizziness (frequency is common). If you become dizzy (light-headed) after your injection, you should sit or lie down until you feel better. If you do not feel better, you should call a doctor before you continue treatment. Cases of fainting have been reported in association with teriparatide use.

If you experience discomfort such as redness of the skin, pain, swelling, itching, bruising or minor bleeding around the area of the injection (frequency is common), this should clear up in a few days or weeks. Otherwise tell your doctor as soon as possible.

Some patients may have experienced allergic reactions soon after injection, consisting of breathlessness, swelling of the face, rash and chest pain (frequency is rare). In rare cases, serious and potentially life-threatening allergic reactions including anaphylaxis can occur.

Other side effects include:
Common: may affect up to 1 in 10 people

- increase in blood cholesterol levels
- depression
- neuralgic pain in the leg
- feeling faint
- irregular heartbeats
- breathlessness
- increased sweating
- muscle cramps

- loss of energy
- tiredness
- chest pain
- low blood pressure
- heartburn (painful or burning sensation just below the breast bone)
- being sick(vomiting)
- a hernia of the tube that carries food to your stomach
- low haemoglobin or red blood cell count (anaemia)

Uncommon: may affect up to 1 in 100 people
- increased heart rate
- abnormal heart sound
- shortness of breath
- piles haemorrhoids
- accidental loss or leakage of urine
- increased need to pass water
- weight increase
- kidney stones
- pain in the muscles and pain in the joints. Some patients have experienced severe back cramps or pain which lead to hospitalisation.
- increase in blood calcium level
- increase in blood uric acid level
- increase in an enzyme called alkaline phosphatase.

Rare: may affect up to 1 in 1,000 people
- reduced kidney function, including renal failure
- swelling, mainly in the hands, feet and legs.

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Sondelbay

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and pen after EXP. The expiry date refers to the last day of that month.

Sondelbay should be stored in a refrigerator (2°C to 8°C). Once opened, Sondelbay can be stored at temperature conditions up to 25°C for a maximum of 3 days when refrigeration is unavailable, after which it should be returned to the refrigerator and used within 28 days of the first injection. Discard Sondelbay, if it has been kept out of refrigerator up to 25°C for more than 3 days

Do not freeze Sondelbay. Avoid placing the pens close to the ice compartment of the refrigerator to prevent freezing. Do not use Sondelbay if it is, or has been, frozen.

Store in original package (i.e. outer carton) in order to protect from light.

Each pen should be disposed of after 28 days of first use, even if it is not completely empty.

Sondelbay contains a clear and colourless solution. Do not use Sondelbay if solid particles appear or if the solution is cloudy or coloured.

Do not transfer the medicine into a syringe.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use These measures will help to protect the environment.

6. Contents of the pack and other information

What Sondelbay contains
- The active substance is teriparatide. Each millilitre of the solution for injection contains 250 micrograms of teriparatide. Each dose of 80 microliters contains 20 micrograms of teriparatide. One pre-filled pen of 2.4 mL contains 600 micrograms of teriparatide.
- The other ingredients are glacial acetic acid, sodium acetate (anhydrous), mannitol, metacresol, and water for injections. In addition, hydrochloric acid and/or sodium hydroxide solution may have been added for pH adjustment (see section 2 “Sondelbay contains sodium”)..

What Sondelbay looks like and contents of the pack
Sondelbay is a colourless and clear solution. It is supplied in a cartridge contained in a pre-filled disposable pen. Each pre-filled pen contains 2.4 mL of solution for 28 doses. Sondelbay is available in packs containing one or three pre-filled pen without needles, and one pre-filled pen with 28 needles. Not all pack sizes may be available.

Marketing Authorisation Holder
Accord Healthcare S.L.U.
World Trade Centre, Moll de Barcelona s/n,
Edifici Est, 6ª Planta,
08039, Barcelona, Spain

Manufacturer(s)

Accord Healthcare Polska Sp.z o.o.,
ul. Lutomierska 50,
95-200 Pabianice,
Poland

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

AT / BE / BG / CY / CZ / DE / DK / EE / FI / FR / HR / HU / IE / IS / IT / LT / LV / LU / MT / NL / NO / PT / PL / RO / SE / SI / SK / ES

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This leaflet was last revised in

Detailed information on this medicine is available on the European Medicines Agency web site: http://www.ema.europa.eu

Pen user manual

Sondelbay 20 micrograms/80 microlitres solution for injection in pre-filled pen
teriparatide

Instructions for Use

Before using your new Sondelbay pen, please read the front and back of these Instructions for Use completely. The back of this page contains troubleshooting and other information.

Follow the instructions carefully when using the Sondelbay pen. Also read the package leaflet provided.

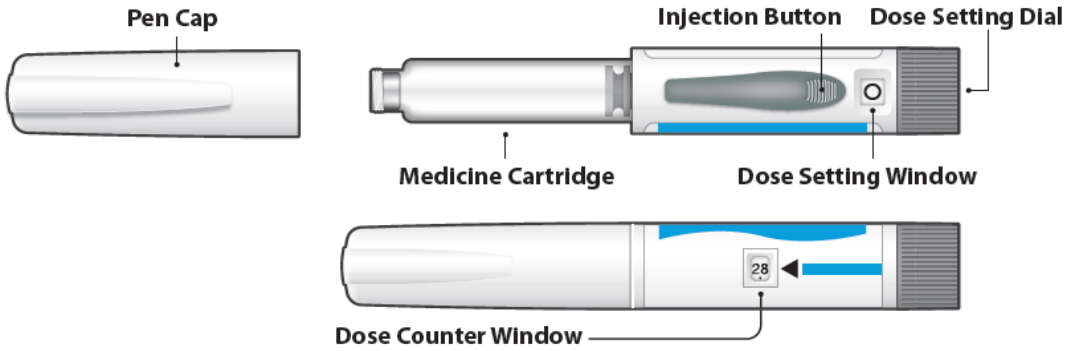
Do not share your Sondelbay pen or your needles with others as infection or disease can spread from one person to another.

Your Sondelbay pen contains 28 days of medicine.

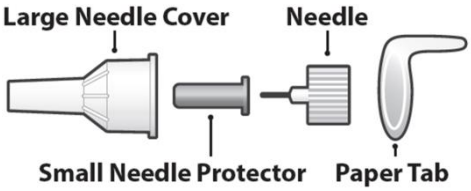
Dispose of your Sondelbay pen 28 days after your first injection, even if it is not completely empty.

Do not inject more than one dose of Sondelbay on the same day.

Sondelbay pen parts



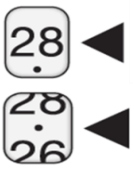
Needles



Use with pen needles (31G or 32G; 4 mm, 5 mm or 8 mm).
Ask your doctor or pharmacist which needle gauge and length are best for you.

Use a new needle for every injection

Check the dose counter window to determine the number of doses remaining. The arrow ◄ points towards the number of doses remaining. A new pen should have 28 doses.

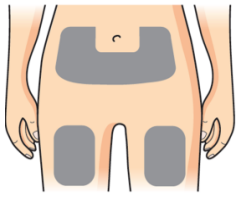


Black dots appearing the dose counter window refer to the odd numbers of doses left in the pen.

Do not use the pen if the dose counter reads ‘00’ as this means there are no doses left.

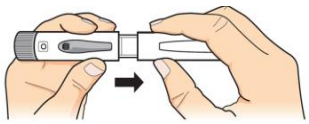
Your Sondelbay pen does not require priming.

1 Prepare



Prepare the injection site (thigh or abdomen) as directed by your doctor or pharmacist.

- **Always** wash your hands before every injection.
- **Check** the pen label to make sure it is the correct medicine.
- **Check** the expiration date to make sure it has not passed.
- **Check** the dose counter window to make sure your pen has doses remaining.
  A new pen should have 28 doses in it.



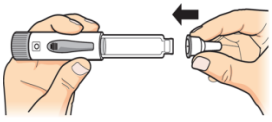
Pull off the pen cap.

- **Check** that the pen, including the medicine cartridge, is not damaged.
- **Check** that the medicine is clear, colourless and free of particles.

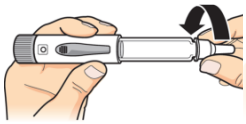
2 Attach new needle



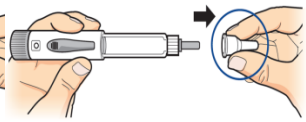
Obtain a new pen needle (see above).
Pull off the paper tab.



Push the needle **straight** onto the medicine cartridge.

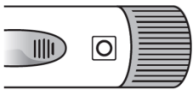


Screw on the needle until **firmly** attached.

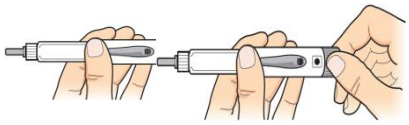


Pull off the large needle cover and **save it**.
You will need it to remove the needle after use.

3 Set dose



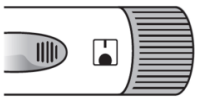
Check that an empty circle sign ⊙ is in the dose setting window.



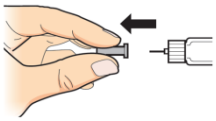
Turn the dose setting dial - firmly clockwise , arrows will be seen in the dose setting window.

Keep turning all the way **and do not release the dose setting dial** until you hear a click and see a **filled circle sign** ⊙ in the dose setting window.

Early release or incomplete rotations can impact the dose counter and result in fewer doses being available from your Sondelbay Pen.

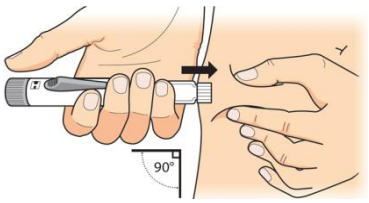


Let go of the dose setting dial. The filled circle with a bar above it ⊙ will be seen in the dose setting window.
This confirms you have set your dose.

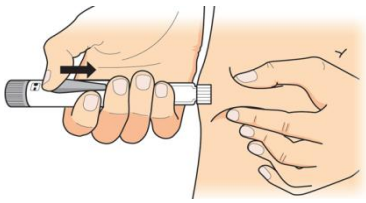


Pull off the small needle protector and **dispose of it**.

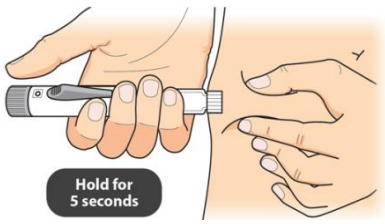
4 Inject dose



Gently hold a fold of skin from the thigh or abdomen. Insert the needle straight into the skin, making sure that the **dose setting window is visible** to you.

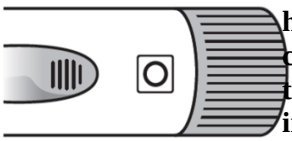


Keep the needle in the skin, **slide** the injection button until it stops. This will start your injection.



Keep the needle in the skin, wait until an empty circle sign ⊙ appears in the dose setting window. Now **count to 5 slowly** then pull the needle from the skin.

5 Confirm dose

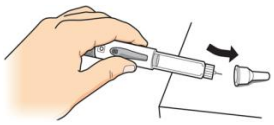


After you have completed the injection and removed the needle from the skin, **check** to make sure that the empty circle sign ⊙ appears in the dose setting window.

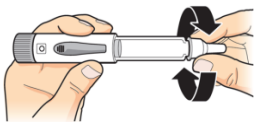
If the empty circle sign **does not** appear in the dose setting window

- **Do not inject a second time on the same day.**
- Instead, you must reset the pen. See Troubleshooting - Problem D.

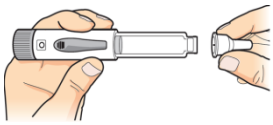
6 Remove needle



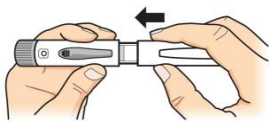
Put the large needle cover on the needle as shown above, then **push** it to secure it in place. To prevent needlestick injuries, **do not** try to re-attach the small needle protector or touch the needle.



Unscrew the needle from the pen by rotating the large needle cover counter clockwise at least 5 times.



Pull off the needle and dispose of it as directed by your doctor or pharmacist.



Push the pen cap back on the pen firmly. Store the pen in the **refrigerator** immediately after use.

Troubleshooting		
	Problem	**Solution**
A.	**I see an air bubble in my Sondelbay pen.**	A small air bubble will not affect your dose, nor will it harm you. You can continue to take your dose as usual.
B.	**I cannot dial my dose.**	1. Check the dose counter window and make sure that your Sondelbay pen has at least one dose left. If you see 00 in the dose counter window, it means that there is no dose remaining in Sondelbay pen. You may still see some medicine left in the cartridge, but it cannot be injected. You should use a new Sondelbay pen to use your next dose. 2. If your Sondelbay pen has at least one dose remaining, and you still cannot dial your dose, make sure you turn the dose setting dial clockwise until you hear a click and see a filled circle sign ● in the dose setting window. Do not let go of the dose setting dial until you hear the click and see a filled circle sign, otherwise it will spring back to its original position. After the click, let go of the dose setting dial and you will see a filled circle sign with a bar on the top ⊕ in the dose setting window.
C.	**I see a drop of medicine at the tip of the needle when I remove the small needle protector for injection.**	A small drop of medicine at the tip of the needle will not affect your dose. Continue to use your dose as described in the Step 4 of Instructions for Use.
D.	**The empty circle sign ⊙ did not appear in the dose setting window even after I pushed the injection button all the way and waited. What should I do?**	**You should reset your Sondelbay pen by following the steps below:** 1. **If you have already administered an injection, DO NOT inject yourself a second time on the same day**. 2. Remove the used needle by carefully re-attaching the large needle cover over the needle. **Do not** touch the needle. **Do not** try to re-attach the small needle protector. Unscrew the needle and dispose of it as directed by your doctor or pharmacist. 3. Attach a new needle, pull off the large needle cover and save it. 4. Point the small needle protector towards an empty container. 5. Pull off the small needle protector. Be careful, this may spray some medicine. It may also be possible that some medicine has already been squirted into the small needle protector. Dispose of the small needle protector. 6. You should now see the empty circle sign in the dose setting window. If you still cannot see it, please contact your doctor or pharmacist. 7. Put the large needle cover on the needle. Do not touch the needle. **Do not** try to re-attach the small needle protector. Unscrew the needle and dispose of it as directed by your doctor or pharmacist. 8. Put the pen cap back on the Sondelbay pen, and place your Sondelbay pen in the refrigerator. 9. Wash your hands.

		You can prevent this problem by always using a NEW needle for every injection, and by sliding the injection button until it stops. **Wait for the empty circle sign to appear then count to 5 slowly before removing the needle from the skin.**
E.	**How can I tell if my Sondelbay pen works?**	Your Sondelbay pen is designed to inject the full dose every time you use it as per the Instructions for Use. The empty circle sign ⊙ is shown in the **dose setting window** following the injection to indicate that the full dose of medicine has been injected. The **dose counting window** displays the number of doses remaining in the pen. This will count down by 1 each time an injection is given. This will also indicate that the pen is working. Use a new needle for every injection to be sure your Sondelbay pen will work properly.
F.	**I cannot remove the needle from my Sondelbay pen.**	1. Put the large needle cover on the needle as shown in step 6 on the front page. 2. To unscrew the needle, push the needle onto the pen whilst rotating it counter-clockwise multiple times. 3. Pull off the needle and dispose of it as directed by your doctor or pharmacist. 4. If you still cannot get the needle off, ask someone to help you.

Cleaning and storage

Cleaning your Sondelbay pen:

- Wipe the outside of your Sondelbay pen with a damp cloth.
- Do not place your Sondelbay pen in water or clean it with any liquid.

Storing your Sondelbay pen:

- Refer the package leaflet for instructions of storing your Sondelbay pen.

Disposal of Sondelbay pen and needles

Disposal of Sondelbay pen

- Dispose of your Sondelbay pen 28 days after your first injection, even if it is not completely empty.
- Always remove the needle before disposing of your Sondelbay pen.
- Ask your doctor or pharmacist how to dispose of your Sondelbay pen.

Disposal of needles

- Put the used needles in a sharps container or a hard plastic container with a secure lid.
- Do not dispose of needles directly into your household waste.
- Do not recycle the filled sharps container.
- Ask your doctor or pharmacist how to dispose of the sharps container properly.
- These directions regarding needle handling are not intended to replace your local, healthcare professional's or institutional policies.

Other information

• Read and follow the directions in the package leaflet for using the product.
• The Sondelbay pen is not recommended for use by a blind or visually impaired person without the assistance of a person trained in the proper use of the device.
• Keep your Sondelbay pen out of the sight and reach of children.
• Do not transfer the medicine into a syringe.
• Use a new needle for every injection.
• Check your Sondelbay pen label to make sure you have the correct medicine and that it has not expired.
• Contact your doctor or pharmacist if you notice any of the following:
  • Your Sondelbay pen appears damaged
  • Your medicine is NOT clear, colourless and free of particles
• Your Sondelbay pen contains 28 days of medicine.
• Note down your first injection date on the outer carton of Sondelbay pen (see the provided space: date of first use). You should dispose of your Sondelbay pen 28 days after your first injection.

This user manual was last revised in