SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Fondaparinux sodium Dr. Reddy's 10 mg/0.8 ml Solution For Injection in Pre-Filled Syringe

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each pre-filled syringe (0.8 ml) contains 10 mg of fondaparinux sodium.

Excipient(s) with known effect: Contains less than 1 mmol of sodium (23 mg) per dose, and therefore is essentially sodium free.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Solution for injection in pre-filled syringe.
The solution is a clear and colourless to slightly yellow liquid.
pH value: between 5.7 and 7.5.
Osmolality: between 255 and 315 mOsm/kg of water.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Treatment of adults with acute Deep Vein Thrombosis (DVT) and treatment of acute Pulmonary Embolism (PE), except in haemodynamically unstable patients or patients who require thrombolysis or pulmonary embolectomy**.**

4.2 Posology and method of administration

Posology

The recommended dose of fondaparinux is 7.5 mg (patients with body weight ≥ 50, ≤ 100kg) once daily administered by subcutaneous injection. For patients with body weight < 50 kg, the recommended dose is 5 mg. For patients with body weight > 100 kg, the recommended dose is 10 mg.

Treatment should be continued for at least 5 days and until adequate oral anticoagulation is established (International Normalised Ratio 2 to 3).

Concomitant oral anticoagulation treatment should be initiated as soon as possible and usually within 72 hours. The average duration of administration in clinical trials was 7 days and the clinical experience from treatment beyond 10 days is limited.

Special populations

Elderly patients - No dosing adjustment is necessary. In patients ≥75 years, fondaparinux should be used with care, as renal function decreases with age (see section 4.4).

Renal impairment - Fondaparinux should be used with caution in patients with moderate renal impairment (see section 4.4).

There is no experience in the subgroup of patients with *both* high body weight (>100 kg) and moderate renal impairment (creatinine clearance 30-50 ml/min). In this subgroup, after an initial 10 mg daily dose, a reduction of the daily dose to 7.5 mg may be considered, based on pharmacokinetic modelling (see section 4.4).

Fondaparinux should not be used in patients with severe renal impairment (creatinine clearance < 30 ml/min) (see section 4.3).

Hepatic impairment - No dosing adjustment is necessary in patients with either mild or moderate hepatic impairment. In patients with severe hepatic impairment, fondaparinux should be used with care as this patient group has not been studied (see sections 4.4 and 5.2).

Paediatric population - Fondaparinux is not recommended for use in children below 17 years of age due to a lack of data on safety and efficacy (see sections 5.1 and 5.2).

Method of administration

Fondaparinux is administered by deep subcutaneous injection while the patient is lying down. Sites of administration should alternate between the left and the right anterolateral and left and right posterolateral abdominal wall. To avoid the loss of medicinal product when using the pre-filled syringe do not expel the air bubble from the syringe before the injection. The whole length of the needle should be inserted perpendicularly into a skin fold held between the thumb and the forefinger; the skin fold should be held throughout the injection.

For additional instructions for use and handling and disposal see section 6.6.

4.3 Contraindications

- hypersensitivity to the active substance or to any of the excipients listed in section 6.1

- active clinically significant bleeding
- acute bacterial endocarditis
- severe renal impairment defined by creatinine clearance < 30 ml/min.

4.4 Special warnings and precautions for use

Fondaparinux is intended for subcutaneous use only. Do not administer intramuscularly.

There is limited experience from treatment with fondaparinux in haemodynamically unstable patients and no experience in patients requiring thrombolysis, embolectomy or insertion of a vena cava filter.

Haemorrhage
Fondaparinux should be used with caution in patients who have an increased risk of haemorrhage, such as those with congenital or acquired bleeding disorders (e.g. platelet count <50,000/mm^3), active ulcerative gastrointestinal disease and recent intracranial haemorrhage or shortly after brain, spinal or ophthalmic surgery and in special patient groups as outlined below.

As for other anticoagulants, fondaparinux should be used with caution in patients who have undergone recent surgery (<3 days) and only once surgical haemostasis has been established**.**

Agents that may enhance the risk of haemorrhage should not be administered concomitantly with fondaparinux. These agents include desirudin, fibrinolytic agents, GP IIb/IIIa receptor antagonists, heparin, heparinoids, or Low Molecular Weight Heparin (LMWH). During treatment of VTE, concomitant therapy with vitamin K antagonist should be administered in accordance with the information of Section 4.5. Other antiplatelet medicinal products (acetylsalicylic acid, dipyridamole, sulfinpyrazone, ticlopidine or clopidogrel), and NSAIDs should be used with caution. If co- administration is essential, close monitoring is necessary.

Spinal / Epidural anaesthesia
In patients receiving fondaparinux for treatment of VTE rather than prophylaxis, spinal/epidural anaesthesia in case of surgical procedures should not be used.

Elderly patients
The elderly population is at increased risk of bleeding. As renal function generally decreases with age, elderly patients may show reduced elimination and increased exposure of fondaparinux (see section 5.2). Incidences of bleeding events in patients receiving the recommended regimen in the treatment of DVT or PE and aged <65 years, 65-75 and >75 years were 3.0 %, 4.5 % and 6.5 %, respectively. The corresponding incidences in patients receiving the recommended regimen of enoxaparin in the treatment of DVT were 2.5%, 3.6% and 8.3% respectively, while the incidences in patients

receiving the recommended regimen of UFH in the treatment of PE were 5.5%, 6.6% and 7.4%, respectively. Fondaparinux should be used with caution in elderly patients (see section 4.2).

Low body weight
Clinical experience is limited in patients with body weight <50 kg. Fondaparinux should be used with caution at a daily dose of 5 mg in this population (see sections 4.2 and 5.2).

Renal impairment
The risk of bleeding increases with increasing renal impairment. Fondaparinux is known to be excreted mainly by the kidney. Incidences of bleeding events in patients receiving the recommended regimen in the treatment of DVT or PE with normal renal function, mild renal impairment, moderate renal impairment and severe renal impairment were 3.0 % (34/1,132), 4.4 % (32/733), 6.6% (21/318), and 14.5 % (8/55) respectively. The corresponding incidences in patients receiving the recommended regimen of enoxaparin in the treatment of DVT were 2.3% (13/559), 4.6% (17/368), 9.7% (14/145) and 11.1% (2/18) respectively, and in patients receiving the recommended regimen of unfractionated heparin in the treatment of PE were 6.9% (36/523), 3.1% (11/352), 11.1% (18/162) and 10.7% (3/28), respectively.

Fondaparinux is contra-indicated in severe renal impairment (creatinine clearance <30 ml/min) and should be used with caution in patients with moderate renal impairment (creatinine clearance 30-50 ml/min). The duration of treatment should not exceed that evaluated during clinical trial (mean 7 days) (see sections 4.2, 4.3 and 5.2).

There is no experience in the subgroup of patients with both high body weight (>100 kg) and moderate renal impairment (creatinine clearance 30-50 ml/min). Fondaparinux should be used with care in these patients. After an initial 10 mg daily dose, a reduction of the daily dose to 7.5 mg may be considered, based on pharmacokinetic modelling (see section 4.2).

Severe hepatic impairment
The use of fondaparinux should be considered with caution because of an increased risk of bleeding due to a deficiency of coagulation factors in patients with severe hepatic impairment (see section 4.2).

Patients with Heparin Induced Thrombocytopenia
Fondaparinux should be used with caution in patients with a history of HIT. The efficacy and safety of fondaparinux have not been formally studied in patients with HIT type II. Fondaparinux does not bind to platelet factor 4 and does not cross-react with sera from patients with Heparin Induced Thrombocytopenia (HIT) type II. However, rare spontaneous reports of HIT in patients treated with fondaparinux have been received. To date a causal association between treatment with fondaparinux and the occurrence of HIT has not been established.

4.5 Interaction with other medicinal products and other forms of interaction

Bleeding risk is increased with concomitant administration of fondaparinux

and agents that may enhance the risk of haemorrhage (see section 4.4).

In clinical studies performed with fondaparinux, oral anticoagulants (warfarin) did not interact with the pharmacokinetics of fondaparinux; at the 10 mg dose used in the interaction studies, fondaparinux did not influence the anticoagulation monitoring (INR) activity of warfarin.

Platelet inhibitors (acetylsalicylic acid), NSAIDs (piroxicam) and digoxin did not interact with the pharmacokinetics of fondaparinux. At the 10 mg dose used in the interaction studies, fondaparinux did not influence the bleeding time under acetylsalicylic acid or piroxicam treatment, nor the pharmacokinetics of digoxin at steady state.

4.6 Fertility, pregnancy and lactation

Pregnancy
No clinical data on exposed pregnancies are available. Animal studies are insufficient with respect to effects on pregnancy, embryo/foetal development, parturition and postnatal development because of limited exposure. Fondaparinux should not be prescribed to pregnant women unless clearly necessary.

Breastfeeding
Fondaparinux is excreted in rat milk but it is not known whether fondaparinux is excreted in human milk. Breastfeeding is not recommended during treatment with fondaparinux. Oral absorption by the child is however unlikely.

Fertility
There are no data available on the effect of fondaparinux on human fertility. Animal studies do not show any effect on fertility.

4.7 Effects on ability to drive and use machines

No studies on the effect on the ability to drive and to use machines have been performed.

4.8 Undesirable effects

The most commonly reported serious adverse reactions reported with fondaparinux are bleeding complications (various sites including rare cases of intracranial/ intracerebral and retroperitoneal bleedings). Fondaparinux should be used with caution in patients who have an increased risk of haemorrhage (see section 4.4).

The safety of fondaparinux has been evaluated in 2,517 patients treated for

Venous Thrombo-Embolism and treated with fondaparinux for an average of 7 days. The most common adverse reactions were bleeding complications (see section 4.4).

The adverse reactions reported by the investigator as at least possibly related to fondaparinux are presented within each frequency grouping (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) and system organ class by decreasing order of seriousness.

System organ class MedDRA	**Adverse reactions in patients treated for VTE[1]**
Blood and lymphatic system disorders	*Common:* bleeding (gastrointestinal, haematuria, haematoma, epistaxis, haemoptysis, utero-vaginal haemorrhage, haemarthrosis, ocular, purpura, bruise) *Uncommon:* anaemia, thrombocytopaenia *Rare:* other bleeding (hepatic, retroperitoneal, intracranial/intracerebral),
Immune system disorders	*Rare:* allergic reaction (including very rare reports of angioedema, anaphylactoid/anaphylactic reaction)
Metabolism and nutrition	*Rare:* non-protein-nitrogen (Npn)[2] increased
Nervous system disorders	*Uncommon*: headache *Rare:* dizziness
Gastrointestinal disorders	*Uncommon:* nausea, vomiting *Rare:* abdominal pain
Hepatobiliary disorders	*Uncommon*: abnormal liver function, hepatic enzymes increased
Skin and subcutaneous tissue disorders	*Rare:* rash erythematous, pruritus
General disorders and administration site conditions	*Uncommon:* pain, oedema, *Rare:* reaction at injection site

(1) Isolated AEs have not been considered except if they were medically relevant.
(2) Npn stands for non-protein-nitrogen such as urea, uric acid, amino acid, etc.

In post marketing experience, rare cases of gastritis, constipation, diarrhoea and bilirubinaemia have been reported.

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 Yellow Card Scheme, website: www.mhra.gov.uk/yellowcard.

4.9 Overdose

Fondaparinux doses above the recommended regimen may lead to an increased risk of bleeding. There is no known antidote to fondaparinux.

Overdose associated with bleeding complications should lead to treatment discontinuation and search for the primary cause. Initiation of appropriate therapy such as surgical haemostasis, blood replacements, fresh plasma transfusion, plasmapheresis should be considered.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: antithrombotic agents. ATC code: B01AX05

Pharmacodynamic effects

Fondaparinux is a synthetic and selective inhibitor of activated Factor X (Xa). The antithrombotic activity of fondaparinux is the result of antithrombin III (antithrombin) mediated selective inhibition of Factor Xa. By binding selectively to antithrombin, fondaparinux potentiates (about 300 times) the innate neutralization of Factor Xa by antithrombin. Neutralisation of Factor Xa interrupts the blood coagulation cascade and inhibits both thrombin formation and thrombus development. Fondaparinux does not inactivate thrombin (activated Factor II) and has no effects on platelets.

At the doses used for treatment, fondaparinux does not**,** to a clinically relevant extent, affect routine coagulation tests such as activated partial thromboplastin time (aPTT), activated clotting time (ACT) or prothrombin time (PT)/International Normalised Ratio (INR) tests in plasma nor bleeding time or fibrinolytic activity. However, rare spontaneous reports of aPTT prolongation have been received. At higher doses, moderate changes in aPTT can occur. At the 10 mg dose used in interaction studies, fondaparinux did not significantly influence the anticoagulation activity (INR) of warfarin.

Fondaparinux does not cross-react with sera from patients with heparin-induced thrombocytopaenia.

Clinical studies

The fondaparinux clinical program in treatment of Venous Thromboembolism was designed to demonstrate the efficacy of fondaparinux for the treatment of deep vein thrombosis (DVT) and pulmonary embolism (PE). Over 4,874 patients were studied in controlled Phase II and III clinical studies.

Treatment of Deep Venous Thrombosis
In a randomised, double-blind, clinical trial in patients with a confirmed diagnosis of acute symptomatic DVT, fondaparinux 5 mg (body weight < 50 kg), 7.5 mg (body weight ≥ 50 kg, ≤ 100 kg) or 10 mg (body weight >100 kg) SC once daily was compared to enoxaparin sodium 1 mg/kg SC twice daily. A total of 2,192 patients were treated; for both groups, patients were treated for at least 5 days and up to 26 days (mean 7 days). Both treatment groups received Vitamin K antagonist therapy usually initiated within 72 hours after the first study drug administration and continued for 90 ± 7 days, with regular dose adjustments to achieve an INR of 2-3. The primary efficacy endpoint was the composite of confirmed symptomatic recurrent non-fatal VTE and fatal VTE reported up to Day 97. Treatment with fondaparinux was demonstrated to be non-inferior to enoxaparin (VTE rates 3.9% and 4.1%, respectively).

Major bleeding during the initial treatment period was observed in 1.1% of fondaparinux patients, compared to 1.2% with enoxaparin.

Treatment of Pulmonary Embolism
A randomised, open-label, clinical trial was conducted in patients with acute symptomatic PE. The diagnosis was confirmed by objective testing (lung scan, pulmonary angiography or spiral CT scan).
Patients who required thrombolysis or embolectomy or vena cava filter were excluded. Randomised patients could have been pre-treated with UFH during the screening phase but patients treated for more than 24 hours with therapeutic dose of anticoagulant or with uncontrolled hypertension were excluded. Fondaparinux 5 mg (body weight < 50 kg), 7.5 mg (body weight ≥ 50kg, ≤ 100 kg) or 10 mg (body weight >100 kg) SC once daily was compared to unfractionated heparin IV bolus (5,000 IU) followed by a continuous IV infusion adjusted to maintain 1.5–2.5 times aPTT control value. A total of 2,184 patients were treated; for both groups, patients were treated for at least 5 days and up to 22 days (mean 7 days). Both treatment groups received Vitamin K antagonist therapy usually initiated within 72 hours after the first study drug administration and continued for 90 ± 7 days, with regular dose adjustments to achieve an INR of 2-3. The primary efficacy endpoint was the composite of confirmed symptomatic recurrent non-fatal VTE and fatal VTE reported up to Day 97. Treatment with fondaparinux was demonstrated to be non-inferior to unfractionated heparin (VTE rates 3.8% and 5.0%, respectively).

Major bleeding during the initial treatment period was observed in 1.3% of fondaparinux patients, compared to 1.1% with unfractionated heparin.

A pilot dose-finding and pharmacokinetic study of fondaparinux in children with deep vein thrombosis

In an open-label study, 24 paediatric patients (n=10, age 1 to ≤ 5 years weight range 8-20 kg; n=7, age 6 to ≤ 12 years weight range 17-47 kg and n=7 age 13 to ≤ 18 years weight range 47-130 kg) diagnosed with venous thrombosis at study entry were administered fondaparinux. The majority of patients were Hispanic (67%) and 58% were male. Fondaparinux was administered at an initial dose of 0.1 mg/kg subcutaneously once daily and dosing was adjusted to achieve peak fondaparinux sodium concentrations of 0.5 to 1 mg/L after 4 hours. The median duration of treatment in this study was 3.5 days. The majority of patients (88%) achieved target fondaparinux concentrations at 4 hours after the first dose of fondaparinux. Two patients had reports of bleeding during the study. One experienced hypertensive encephalopathy accompanied by intracranial bleeding on day 5 of therapy resulting in fondaparinux discontinuation. Minor gastrointestinal bleeding was reported in another patient on day 5 of therapy which resulted in temporary discontinuation of fondaparinux. No conclusion can be drawn with regard to clinical efficacy in this uncontrolled study.

5.2 Pharmacokinetic properties

The pharmacokinetics of fondaparinux sodium are derived from fondaparinux plasma concentrations quantified via anti factor Xa activity. Only fondaparinux can be used to calibrate the anti-Xa assay (the international standards of heparin or LMWH are not appropriate for this use). As a result, the concentration of fondaparinux is expressed as milligrams (mg).

Absorption

After subcutaneous dosing, fondaparinux is completely and rapidly absorbed (absolute bioavailability 100%). Following a single subcutaneous injection of fondaparinux 2.5 mg to young healthy subjects, peak plasma concentration (mean C_{max} = 0.34 mg/l) is obtained 2 hours post-dosing. Plasma concentrations of half the mean C_{max} values are reached 25 minutes post-dosing.

In elderly healthy subjects, pharmacokinetics of fondaparinux is linear in the range of 2 to 8 mg by subcutaneous route. Following once daily dosing, steady state of plasma levels is obtained after 3 to 4 days with a 1.3-fold increase in C_{max} and AUC.

Mean (CV%) steady state pharmacokinetic parameters estimates of fondaparinux in patients undergoing hip replacement surgery receiving fondaparinux 2.5 mg once daily are: C_{max} (mg/l) - 0.39 (31%), T_{max} (h) - 2.8 (18%) and C_{min} (mg/l) -0.14 (56%). In hip fracture patients, associated with their increased age, fondaparinux steady state plasma concentrations are: C_{max} (mg/l) - 0.50 (32%), C_{min} (mg/l) - 0.19 (58%).

In DVT and PE treatment, patients receiving fondaparinux 5 mg (body weight <50 kg), 7.5 mg (body weight 50-100 kg inclusive) and 10 mg (body weight >100 kg) once daily, the body weight-adjusted doses provide similar exposure

across all body weight categories. The mean (CV%) steady state pharmacokinetic parameters estimates of fondaparinux in patients with VTE receiving the fondaparinux proposed dose regimen once daily are: C_{max} (mg/l) - 1.41 (23 %), T_{max} (h) – 2.4 (8%) and C_{min} (mg/l) -0.52 (45 %). The associated 5th and 95th percentiles are, respectively, 0.97 and 1.92 for C_{max} (mg/l), and 0.24 and 0.95 for C_{min} (mg/l).

Distribution
The distribution volume of fondaparinux is limited (7-11 litres). *In vitro*, fondaparinux is highly and specifically bound to antithrombin protein with a dose-dependant plasma concentration binding (98.6% to 97.0% in the concentration range from 0.5 to 2 mg/l). Fondaparinux does not bind significantly to other plasma proteins, including platelet factor 4 (PF4).

Since fondaparinux does not bind significantly to plasma proteins other than antithrombin, no interaction with other medicinal products by protein binding displacement are expected.

Biotransformation
Although not fully evaluated, there is no evidence of fondaparinux metabolism and in particular no evidence for the formation of active metabolites.

Fondaparinux does not inhibit CYP450s (CYP1A2, CYP2A6, CYP2C9, CYP2C19, CYP2D6, CYP2E1 or CYP3A4) *in vitro*. Thus, fondaparinux is not expected to interact with other medicinal products *in vivo* by inhibition of CYP-mediated metabolism.

Excretion/Elimination
The elimination half-life ($t_{½}$) is about 17 hours in healthy young subjects and about 21 hours in healthy elderly subjects. Fondaparinux is excreted to 64 – 77 % by the kidney as unchanged compound.

<u>*Special populations*</u>

Paediatric patients - Limited data are available in paediatric patients (see section 5.1).

Elderly patients - Renal function may decrease with age and thus, the elimination capacity for fondaparinux may be reduced in elderly. In patients >75 years undergoing orthopaedic surgery and receiving fondaparinux 2.5 mg once daily, the estimated plasma clearance was 1.2 to 1.4 times lower than in patients <65 years. A similar pattern is observed in DVT and PE treatment patients.

Renal impairment - Compared with patients with normal renal function (creatinine clearance > 80 ml/min) undergoing orthopaedic surgery and receiving fondaparinux 2.5 mg once daily, plasma clearance is 1.2 to 1.4 times lower in patients with mild renal impairment (creatinine clearance 50 to 80 ml/min) and on average 2 times lower in patients with moderate renal impairment (creatinine clearance 30 to 50 ml/min). In severe renal impairment

(creatinine clearance <30 ml/min), plasma clearance is approximately 5 times lower than in normal renal function. Associated terminal half-life values were 29 h in moderate and 72 h in patients with severe renal impairment. A similar pattern is observed in DVT and PE treatment patients.

Body weight - Plasma clearance of fondaparinux increases with body weight (9% increase per 10 kg).

Gender - No gender differences were observed after adjustment for body weight.

Race - Pharmacokinetic differences due to race have not been studied prospectively. However, studies performed in Asian (Japanese) healthy subjects did not reveal a different pharmacokinetic profile compared to Caucasian healthy subjects. Similarly, no plasma clearance differences were observed between black and Caucasian patients undergoing orthopaedic surgery.

Hepatic impairment - Following a single, subcutaneous dose of fondaparinux in subjects with moderate hepatic impairment (Child-Pugh Category B), total (i.e., bound and unbound) C_{max} and AUC were decreased by 22% and 39%, respectively, as compared to subjects with normal liver function. The lower plasma concentrations of fondaparinux were attributed to reduced binding to ATIII secondary to the lower ATIII plasma concentrations in subjects with hepatic impairment thereby resulting in increased renal clearance of fondaparinux. Consequently, unbound concentrations of fondaparinux are expected to be unchanged in patients with mild to moderate hepatic impairment, and therefore, no dose adjustment is necessary based on pharmacokinetics.

The pharmacokinetics of fondaparinux has not been studied in patients with severe hepatic impairment (see sections 4.2 and 4.4).

5.3 Preclinical safety data

Non-clinical data reveal no special hazard for humans based on conventional studies of safety pharmacology and genotoxicity. The repeated dose and reproduction toxicity studies did not reveal any special risk but did not provide adequate documentation of safety margins due to limited exposure in the animal species**.**

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium chloride
Water for injections
Hydrochloric acid (for pH-adjustment)
Sodium hydroxide (for pH-adjustment)

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.

6.4 Special precautions for storage

This medicinal product does not require any special storage conditions.

6.5 Nature and contents of container

Type I clear glass barrel (1 ml) affixed with a needle and stoppered with a chlorobutyl elastomer plunger stopper, packed in tray pack in a carton.

Fondaparinux is available in pack sizes of 2, 7, 10, 20 and 30 pre-filled syringes.

Not all pack sizes may be marketed.

The different strengths of the medicinal product can be identified by a different coloured plunger rod:
Fondaparinux sodium 10 mg/0.8 ml: syringe with a violet plunger rod and an automatic safety system.

6.6 Special precautions for disposal

The subcutaneous injection is administered in the same way as with a classical syringe.

Parenteral solutions should be inspected visually for particulate matter and discoloration prior to administration.

Instruction on self-administration is included in the Package Leaflet.

The rigid needle shield of the Fondaparinux sodium 10 mg/0.8 ml solution for injection, pre-filled syringe is used to protect from needle stick injuries following injection.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.
This medicinal product is for single use only.

7 MARKETING AUTHORISATION HOLDER

Dr. Reddy´s Laboratories (UK) Ltd.
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8 MARKETING AUTHORISATION NUMBER(S)

PL 08553/0553

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

08/12/2020

10 DATE OF REVISION OF THE TEXT

05/09/2023