# SUMMARY OF PRODUCT CHARACTERISTICS

## 1 NAME OF THE MEDICINAL PRODUCT

Furosemide 20mg Tablets

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Furosemide BP 20mg

For excipients, see 6.1

## 3 PHARMACEUTICAL FORM

Tablet
White, circular, flat tablets with a breakline and F20 on one side and CP on the other.

## 4 CLINICAL PARTICULARS

### 4.1 Therapeutic indications

Furosemide tablets are recommended for use in all indications when prompt diuresis is required.

Indications include cardiac, pulmonary, hepatic, renal and peripheral oedema and oliguria due to chronic renal failure or insufficiency.

Furosemide may be effective in patients unresponsive to thiazide diuretics.

Furosemide is also used in the treatment of hypertension, either alone or with other antihypertensive agents and in the urgent treatment of hypercalcaemia to promote urinary excretion following rehydration.

## 4.2 Posology and method of administration

**For oral administration**

**OEDEMA**

**Adults & Elderly**

Initially 40mg in the morning adjusted according to response; maintenance 20mg daily or 40mg on alternate days, increased in resistant oedema to 80mg or more as one or two doses daily or intermittently. Severe cases may require titration of the furosemide dosage up to 600mg daily.

**Children**

1-3mg/kg body weight daily up to a maximum of 40mg daily.

**OLIGURIA**

**Adults & Elderly**

Initially 250mg daily; if necessary larger doses, increasing in steps of 250mg, may be given every 4-6 hours to a maximum of a single dose of 2g (rarely used).

**HYPERTENSION**

**Adults & Elderly**

40-80mg daily by mouth alone or with other antihypertensive agents.

## 4.3 Contraindications

- Hypersensitivity to furosemide, or to any of the excipients listed in section 6.1
- Hypersensitivity to amiloride, sulphonamides or sulphonamide derivatives
- Hypovolaemia and dehydration (with or without accompanying hypotension) (see section 4.4)

- Severe hypokalaemia: severe hyponatraemia (see section 4.4).
- Comatose or pre-comatose states associated with hepatic cirrhosis (see section 4.4).
- Anuria or renal failure with anuria not responding to furosemide, renal failure as a result of poisoning by nephrotoxic or hepatotoxic agents or renal failure associated with hepatic coma
- Impaired renal function with a creatinine clearance below 30ml/min per 1.73 $m^2$ body surface area (see section 4.4).
- Addison's disease (see section 4.4).
- Digitalis intoxication (see section 4.5).
- Concomitant potassium supplements or potassium sparing diuretics (see section 4.5).
- Porphyria
- Breast-feeding women (see section 4.6).

## 4.4 Special warnings and precautions for use

**Conditions requiring correction before furosemide is started (see also section 4.3)**

- Hypotension.
- Hypovolaemia.
- Severe electrolyte disturbances – particularly hypokalaemia, hyponatraemia and acid-base disturbances.

**Furosemide is not recommended**

- In patients at high risk for radiocontrast nephropathy - it should not be used for diuresis as part of the preventative measures against radiocontrast-induced nephropathy.
- In patients with rare hereditary problems of glucose-galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption.

**Particular caution and/or dose reduction required:**

Symptomatic hypotension leading to dizziness, fainting or loss of consciousness can occur in patients treated with furosemide, particularly in the elderly, patients on other medications which can cause hypotension and patients with other medical conditions that are risks for hypotension

- elderly patients (lower initial dose as particularly susceptible to side-effects - see section 4.2)

- difficulty with micturition including prostatic hypertrophy (increased risk of urinary retention: consider lower dose). Closely monitor patients with partial occlusion of the urinary tract
- diabetes mellitus (latent diabetes may become overt: insulin requirements in established diabetes may increase: stop furosemide before a glucose tolerance test)
- pregnancy (see section 4.6)
- gout (furosemide may raise uric acid levels/precipitate gout)
- patients with hepatorenal syndrome
- impaired hepatic function (see section 4.3 and below – monitoring required)
- impaired renal function (see section 4.3 and below – monitoring required)
- adrenal disease (see section 4.3 – contraindication in Addison's disease)
- hypoproteinaemia e.g. nephrotic syndrome (effect of furosemide may be impaired and its ototoxicity potentiated - cautious dose titration required).
- acute hypercalcaemia (dehydration results from vomiting and diuresis - correct before giving furosemide). Treatment of hypercalcaemia with a high dose of furosemide results in fluid and electrolyte depletion - meticulous fluid replacement and correction of electrolyte required.
- Patients who are at risk from a pronounced fall in blood pressure
- Premature infants (Furosemide may cause nephrocalcinosis/ nephrolithiasis; renal function must be monitored and renal ultrasonography performed).

**Avoidance with other medicines (see also section 4.5 for other interactions)**

- concurrent NSAIDs should be avoided – if not possible diuretic effect of furosemide may be attenuated
- ACE-inhibitors & Angiotensin II receptor antagonists – severe hypotension may occur – dose of furosemide should be reduced/stopped (3 days) before starting or increasing the dose of these

**Laboratory monitoring requirements:**

- Serum sodium

Particularly in the elderly or in patients liable to electrolyte deficiency

- Serum potassium

The possibility of hypokalaemia should be taken into account, in particular in patients with cirrhosis of the liver, those receiving concomitant treatment with corticosteroids, those with an unbalanced diet and those who abuse laxatives. Regular monitoring of the potassium, and if necessary treatment with a potassium supplement, is recommended in all cases, but is essential at higher doses and in patients with impaired renal function. It is especially important in the event of concomitant

treatment with digoxin, as potassium deficiency can trigger or exacerbate the symptoms of digitalis intoxication (see section 4.5). A potassium-rich diet is recommended during long-term use.

Frequent checks of the serum potassium are necessary in patients with impaired renal function and creatinine clearance below 60ml/min per 1.73m2 body surface area as well as in cases where furosemide is taken in combination with certain other drugs which may lead to an increase in potassium levels (see section 4.5 & refer to section 4.8 for details of electrolyte and metabolic abnormalities)

- Renal function

Frequent BUN in first few months of treatment, periodically thereafter. Long-term/high-dose BUN should regularly be measured. Marked diuresis can cause reversible impairment of kidney function in patients with renal dysfunction. Adequate fluid intake is necessary in such patients. Serum creatinine and urea levels tend to rise during treatment

- Glucose

Adverse effect on carbohydrate metabolism - exacerbation of existing carbohydrate intolerance or diabetes mellitus. Regular monitoring of blood glucose levels is desirable.

- Other electrolytes

Patients with hepatic failure/alcoholic cirrhosis are particularly at risk of hypomagnesia (as well as hypokalaemia). During long-term therapy (especially at high doses) magnesium, calcium, chloride, bicarbonate and uric acid should be regularly measured.

**Clinical monitoring requirements (see also section 4.8):**

Regular monitoring for

- blood dyscrasias. If these occur, stop furosemide immediately
- liver damage
- idiosyncratic reactions

**Other alterations in lab values**

- Serum cholesterol and triglycerides may rise but usually return to normal within 6 months of starting furosemide

**Concomitant use with risperidone**

In risperidone placebo-controlled trials in elderly patients with dementia, a higher incidence of mortality was observed in patients treated with furosemide plus risperidone (7.3%; mean age 89 years, range 75-97 years) when compared to patients

treated with risperidone alone (3.1%; mean age 84 years, range 70-96 years) or furosemide alone (4.1%; mean age 80 years, range 67-90 years). Concomitant use of risperidone with other diuretics (mainly thiazide diuretics used in low dose) was not associated with similar findings.

No pathophysiological mechanism has been identified to explain this finding, and no consistent pattern for cause of death observed. Nevertheless, caution should be exercised and the risks and benefits of this combination or co-treatment with other potent diuretics should be considered prior to the decision to use. There was no increased incidence of mortality among patients taking other diuretics as concomitant treatment with risperidone. Irrespective of treatment, dehydration was an overall risk factor for mortality and should therefore be avoided in elderly patients with dementia (see section 4.3 Contraindications).

## 4.5 Interaction with other medicinal products and other forms of interaction

*General:* The dosage of concurrently administered cardiac glycosides, diuretics, anti-hypertensive agents, or other drugs with blood-pressure-lowering potential may require adjustment as a more pronounced fall in blood pressure must be anticipated if given concomitantly with furosemide.

The toxic effects of nephrotoxic drugs may be increased by concomitant administration of potent diuretics such as furosemide.

Some electrolyte disturbances (e.g. hypokalaemia, hypomagnesaemia) may increase the toxicity of certain other drugs (e.g. digitalis preparations and drugs inducing QT interval prolongation syndrome).

*Antihypertensives:* enhanced hypotensive effect possible with all types. Concurrent use with ACE inhibitors or Angiotensin II receptor antagonists can result in marked falls in blood pressure, furosemide should be stopped or the dose reduced before starting an ACE-inhibitor or Angiotensin II receptor antagonists (see section 4.4)

*Antipsychotics:* furosemide-induced hypokalaemia increases the risk of cardiac toxicity. Avoid concurrent use with pimozide. Increased risk of ventricular arrhythmias with amisulpride or sertindole. Enhanced hypotensive effect with phenothiazines.

When administering risperidone, caution should be exercised and the risks and benefits of the combination or co-treatment with furosemide or with other potent diuretics should be considered prior to the decision to use. See section 4.4 Special warnings and precautions for use regarding increased mortality in elderly patients with dementia concomitantly receiving risperidone.

*Anti-arrhythmics (including amiodarone, disopyramide, flecanaide and sotalol):* risk of cardiac toxicity (because of furosemide-induced hypokalaemia). The effects of lidocaine, tocainide or mexiletine may be antagonised by furosemide.

*Cardiac glycosides:* hypokalaemia and electrolyte disturbances (including hypomagnesia) increase the risk of cardiac toxicity.

*Drugs that prolong Q-T interval:* increased risk of toxicity with furosemide-induced electrolyte disturbances

*Vasodilators:* enhanced hypotensive effect with moxisylyte (thymoxamine) or hydralazine

*Other diuretics:* profound diuresis possible when furosemide given with metolazone. Increased risk of hypokalaemia with thiazides. Contraindicated with potassium sparing diuretics (eg Amiloride spironolactone) - increased risk of hyperkalaemia (see section 4.3)

*Renin inhibitors:* aliskiren reduces plasma concentrations of furosemide

*Nitrates:* enhanced hypotensive effect

*Lithium:* In common with other diuretics, serum lithium levels may be increased when lithium is given concomitantly with furosemide, resulting in increased lithium toxicity, including increased risk of cardiotoxic and neurotoxic effects of lithium. Therefore, it is recommended that lithium levels are carefully monitored and where necessary the lithium dosage is adjusted in patients receiving this combination.

*Chelating agents:* sucralfate may decrease the gastro-intestinal absorption of furosemide – the 2 drugs should be taken at least 2 hours apart

*NSAIDs:* increased risk of nephrotoxicity. Indometacin and ketorolac may antagonise the effects of furosemide (avoid if possible see section 4.4)

*Salicylates:* effects may be potentiated by furosemide. Salycylic toxicity may be increased by furosemide

*Antibiotics:* increased risk of ototoxicity with aminoglycosides, polymixins or vancomycin - only use concurrently if compelling reasons. Increased risk of nephrotoxicity with aminoglycosides or cefaloridine. Furosemide can decrease vancomycin serum levels after cardiac surgery. Increased risk of hyponatraemia with trimethoprim. Impairment of renal function may develop in patients receiving concurrent treatment with furosemide and high doses of certain cephalosporins.

*Antidepressants:* enhanced hypotensive effect with MAOIs. Increased risk of postural hypotension with TCAs (tricyclic antidepressants). Increased risk of hypokalaemia with reboxetine

*Antidiabetics:* hypoglycaemic effects antagonised by furosemide

*Antiepileptics:* increased risk of hyponatraemia with carbamazepine. Diuretic effect reduced by phenytoin.

*Antihistamines:* hypokalaemia with increased risk of cardiac toxicity

*Antifungals:* increased risk of hypokalaemia and nephrotoxicity with amphoterecin

*Anxiolytics and hypnotics:* enhanced hypotensive effect. Chloral or triclorfos may displace thyroid hormone from binding site.

*CNS stimulants (drugs used for ADHD):* hypokalaemia increases the risk of ventricular arrhythmias

*Corticosteroids:* diuretic effect anatgonised (sodium retention) and increased risk of hypokalaemia

*Glychyrrizin:* (contained in liquorice) may increase the risk of developing hypokalaemia.

*Carbenoxolone:* may increase the risk of developing hypokalaemia

*Cytotoxics:* increased risk of nephrotoxicity and ototoxicity with platinum compounds/cisplatin. Nephrotoxicity of cisplatin may be enhanced if furosemide is not given in low doses (e.g. 40 mg in patients with normal renal function) and with positive fluid balance when used to achieve forced diuresis during cisplatin treatment.

*Anti-metabolites:* effects of furosemide may be reduced by methotrexate and furosemide may reduce renal clearance of methotrexate

*Potassium salts:* contraindicated - increased risk of hyperkalaemia (see section 4.3)

*Dopaminergics:* enhanced hypotensive effect with levodopa.

*Immunomodulators:* enhanced hypotensive effect with aldesleukin. Increased risk of hyperkalaemia with ciclosprin and tacrolimus. Increased risk of gouty arthritis with ciclosporin

*Muscle relaxants:* enhanced hypotensive effect with baclofen or tizanidine. Increased effect of curare-like muscle relaxants

*Oestrogens:* diuretic effect antagonised

*Progestogens (drosperidone):* increased risk of hyperkalaemia

*Prostaglandins:* enhanced hypotensive effect with alprostadil

*Sympathomimetics:* increased risk of hypokalaemia with high doses of $beta_2$ sympathomimetics

*Theophylline:* enhanced hypotensive effect

*Probenecid:* effects of furosemide may be reduced by probenecid and furosemide may reduce renal clearance of probenecid.

*Anaesthetic agents:* general anaesthetic agents may enhance the hypotensive effects of furosemide. The effects of curare may be enhanced by furosemide.

*Alcohol:* enhanced hypotensive effect

*Laxative abuse:* increases the risk of potassium loss

*Others:* Concomitant administration of aminoglutethimide may increase the risk of hyponatraemia.

## 4.6 Fertility, Pregnancy and lactation

*Pregnancy*

There is clinical evidence of safety of the drug in the third trimester of human pregnancy & furosemide has been given after the first trimester of pregnancy for oedema, hypertension and toxaemia of pregnancy without causing fetal or newborn adverse effects. However, furosemide crosses the placental barrier and should not be given during pregnancy unless there are compelling medical reasons. It should only be used for the pathological causes of oedema which are not directly or indirectly

linked to the pregnancy. The treatment with diuretics of oedema and hypertension caused by pregnancy is undesirable because placental perfusion can be reduced, so, if used, monitoring of fetal growth is required.

*Breast-feeding (see section 4.3)*

Furosemide is contraindicated as it passes into breast milk and may inhibit lactation.

## 4.7 Effects on ability to drive and use machines

Reduced mental alertness, dizziness and blurred vision have been reported, particularly at the start of treatment, with dose changes and in combination with alcohol. Patients should be advised that if affected, they should not drive, operate machinery or take part in activities where these effects could put themselves or others at risk.

## 4.8 Undesirable effects

Undesirable effects can occur with the following frequencies: 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, including isolated reports), not known (cannot be estimated from the available data)

**Blood and lymphatic system disorders:**

Uncommon: thrombocytopenia

Rare: Eosinophilia, leukopenia, bone marrow depression (necessitates withdrawal of treatment). The haemopoietic status should be therefore be regularly monitored.

Very Rare: Aplastic anaemia or haemolytic anaemia, agranulocytosis

**Nervous system disorders:**

Rare: Paraesthesia, hyperosmolar coma

Not known: dizziness, fainting and loss of consciousness (caused by symptomatic hypotension)

**Endocrine disorder:**

Glucose tolerance may decrease with furosemide. In patients with diabetes mellitus this may lead to a deterioration of metabolic control; latent diabetes mellitus may become manifest. Insulin requirements of diabetic patients may increase.

**Eye disorders:**

Uncommon: visual disturbance

**Ear and labyrinth disorders:**

Uncommon: Deafness (sometimes irreversible)

Hearing disorders and tinnitus, although usually transitory, may occur in rare cases, particularly in patients with renal failure, hypoproteinaemia (e.g. in nephritic syndrome) and/or when intravenous furosemide has been given too rapidly.

**Cardiac disorders:**

Uncommon: Cardiac arrhythmias

Furosemide may cause a reduction in blood pressure which, if pronounced may cause signs and symptoms such as impairment of concentration and reactions, light headedness, sensations of pressure in the head, headache, dizziness, drowsiness, weakness, disorders of vision, dry mouth, orthostatic intolerance.

**Hepatobiliary disorders:**

In isolated cases, intrahepatic cholestasis, an increase in liver transaminases or acute pancreatitis may develop.

Hepatic encephalopathy in patients with hepatocellular insufficiency may occur (see Section 4.3).

**Vascular Disorder:**

Rare: Vasculitis

**Skin and subcutaneous tissue disorders:**

Uncommon: Photosensitivity

Rare: Skin and mucous membrane reactions may occasionally occur, e.g. itching, urticaria, other rashes or bullous lesions, fever, hypersensitivity to light, exsudative erythema multiforme (Lyell's syndrome and Stevens-Johnson syndrome), bullous exanthema, exfoliative dermatitis, purpura, and DRESS (Drug rash with eosinophilia and systemic symptoms).

Not known: Acute generalised exanthematous pustulosis (AGEP)

**Metabolism and nutrition disorders:**

As with other diuretics, electrolytes and water balance may be disturbed as a result of diuresis after prolonged therapy. Furosemide leads to increased excretion of sodium and chloride and consequently increase excretion of water. In addition, excretion of other electrolytes (in particular potassium, calcium and magnesium) is increased.

Metabolic acidosis can also occur. The risk of this abnormality increases at higher dosages and is influenced by the underlying disorder (e.g. cirrhosis of the liver, heart failure), concomitant medication (see section 4.5) and diet.

Symptomatic electrolyte disturbances and metabolic alkalosis may develop in the form of a gradually increasing electrolyte deficit or e.g. where higher furosemide doses are administered to patients with normal renal function, acute severe electrolyte losses.

Symptoms of electrolyte imbalance depend on the type of disturbance:

Sodium deficiency can occur; this can manifest itself in the form of confusion, muscle cramps, muscle weakness, loss of appetite, dizziness, drowsiness and vomiting.

Potassium deficiency manifests itself in neuromuscular symptoms (muscular weakness, paralysis), intestinal symptoms (vomiting, constipation, meterorism), renal symptoms (polyuria) or cardiac symptoms. Severe potassium depletion can result in paralytic ileus or confusion, which can result in coma.

Magnesium and calcium deficiency result very rarely in tetany and heart rhythm disturbances.

Serum calcium levels may be reduced; in very rare cases tetany has been observed.

Nephrocalcinosis/Nephrolithiasis has been reported in premature infants.

Serum cholesterol (reduction of serum HDL-cholesterol, elevation of serum LDL-cholesterol) and triglyceride levels may rise during furosemide treatment. During long term therapy they will usually return to normal within six months.

As with other diuretics, treatment with furosemide may lead to transitory increase in blood creatinine and urea levels. Serum levels of uric acid may increase and attacks of gout may occur.

The diuretic action of furosemide may lead to or contribute to hypovolaemia and dehydration, especially in elderly patients. Severe fluid depletion may lead to haemoconcentration with a tendency for thromboses to develop.

*General disorders and administration site conditions:*

Uncommon: Fatigue

Rare: Severe anaphylactic or anaphylactoid reactions (e.g. with shock) occur rarely, fever, malaise

**Gastrointestinal disorders:**

Uncommon: dry mouth, thirst, nausea, bowel motility disturbances, vomiting, diarrhea, constipation.

Gastro-intestinal disorders such as nausea, malaise or gastric upset (vomiting or diarrhoea) and constipation may occur but not usually severe enough to necessitate withdrawal of treatment.

Rare: Acute Pancreatitis

**Renal and urinary disorders:**

Uncommon: Serum creatinine and urea levels can be temporarily elevated during treatment with furosemide.

Rare: Interstitial nephritis, acute renal failure.

Increased urine production, urinary incontinence, can be caused or symptoms can be exacerbated in patients with urinary tract obstruction. Acute urine retention, possibly accompanied by complications, can occur for example in patients with bladder disorders, prostatic hyperplasia or narrowing of the urethra.

**Pregnancy, puerperium and perinatal conditions:**

In premature infants with respiratory distress syndrome, administration of Furosemide Tablets in the initial weeks after birth entails an increased risk of a persistent patent ductus arteriosus.

In premature infants, furosemide can be precipitated as nephrocalcinosis/kidney stones.

Rare complications may include minor psychiatric disturbances.

<u>Reporting of suspected adverse reactions</u>
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 at www.mhra.gov.uk/yellowcard.

## 4.9 Overdose

### Toxicity

The toxicity of diuretics is principally associated with fluid and electrolyte loss. More than a few tablets could cause marked effects, particularly in the elderly, however, adults and children who have ingested less than 2 mg/Kg are unlikely to require medical assessment. Peak diuresis and effects on blood pressure are likely to occur within 2 hours of ingestion.

### Features

Most patients will not develop serious symptoms but overdose may cause acute, profound diuresis (increased frequency of micturition) resulting in dehydration, volume depletion and electrolyte disturbance. Hypotension, tachycardia, cardiac arrhythmia, hypovolaemia, haemoconcentration hypokalaemia, hypomagnaesemia, hypocalcaemia, hyponatraemia and hypochloraemic alkalosis may occur, with electrolyte depletion causing symptoms such as severe hypotension (progressing to shock), acute renal failure, thrombosis, delirious states, flaccid paralysis, apathy, weakness, dizziness, confusion, anorexia, lethargy, vomiting, cramps and dysrhythmias.

Dose related adverse effects during therapy have been reported. Myalgia, arthralgia, muscle cramps and weakness occurred in patients receiving doses of between 2 and 10 mg furosemide. High doses have the potential to cause transient deafness and disturbance of uric acid excretion precipitating gout.

### Management

- The benefit of gastric decontamination is uncertain, however, activated charcoal (50g for adults; 1 g/Kg for children) should be considered if the patient presents within 1 hour of ingesting a toxic dose.
- Observe for a minimum of 4 hours. Monitor BP and pulse.
- Give i.v. fluids for hypotension and dehydration.
- Monitor urinary output and serum electrolyte levels including chloride and bicarbonate. Correct electrolyte imbalances.
- Perform a 12 lead ECG and measure the QRS duration and QT interval. Repeat 12 lead ECG is recommended, especially in symptomatic patients.
- Other measures as indicated by the patient's clinical condition.
- Patients should be advised on discharge to seek medical attention if symptoms subsequently develop.

# 5 PHARMACOLOGICAL PROPERTIES

### 5.1 Pharmacodynamic properties

Furosemide is a diuretic with a rapid action. It exerts inhibiting effects on electrolyte reabsorption in the proximal and distal renal tubules and in the ascending loop of Henle.

### 5.2 Pharmacokinetic properties

Furosemide is incompletely but fairly rapidly absorbed from the gastrointestinal tract. It has a biphasic half-life in the plasma with a terminal elimination phase that has been estimated to range up to about 1½ hours. Furosemide is mainly excreted in the urine. Furosemide crosses the placental barrier and is excreted in milk.

### 5.3 Preclinical safety data

There are no pre-clinical data of relevance to the prescriber which are additional to those included in other sections.

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Lactose

Maize starch

Pregelatinised maize starch

Magnesium stearate

### 6.2 Incompatibilities

None.

### 6.3 Shelf life

36 Months.

### 6.4 Special precautions for storage

Do not store above 25°C

Store in the original container

### 6.5 Nature and contents of container

Polypropylene or polyethylene containers or amber glass bottles containing 50, 100, 250, 500 and 1000 tablets.

Strip packs of opaque white or clear PCV film and 20 micron aluminium foil. The tablets are packed in multiple strips of 10 tablets i.e. 10, 20, 30, 40, 50, 60, 70, 80, 90 and 100 tablets and in multiple strips of 14 tablets i.e. 14, 28, 56, 84 and 112 tablets.

Bulk pack of a plastic container containing 20000 tablets.

### 6.6 Special precautions for disposal

Not applicable.

## 7 MARKETING AUTHORISATION HOLDER

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## 8 MARKETING AUTHORISATION NUMBER(S)

PL 55539/0016

## 9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

09th June 1982 / 7th April 2008

## 10 DATE OF REVISION OF THE TEXT

03/12/2021