Furosemide 20mg Tablets

PL 21880/0112

UKPAR

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Furosemide 20mg Tablets

PL 21880/0112

LAY SUMMARY

The Medicines and Healthcare products Regulatory Agency (MHRA) granted Medreich Plc a Marketing Authorisation (licence) for the medicinal product, Furosemide 20mg Tablets, on 1st December 2010. This is a prescription-only medicine.

Furosemide 20mg Tablets contain furosemide as the active ingredient. This belongs to a group of medicines called diuretics (also called water tablets). Furosemide 20mg Tablets are used to treat oedema (fluid retention) caused by heart failure, mild to moderate hypertension (high blood pressure) and certain liver and kidney disorders. They are also used to manage a condition called oliguria where the body produces an abnormally small amount of urine, due to kidney disease.

No new or unexpected safety concerns arose from this application and it was therefore judged that the benefits of Furosemide 20mg Tablets outweigh the risk; hence a Marketing Authorisation has been granted.
Furosemide 20mg Tablets

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SCIENTIFIC DISCUSSION

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**INTRODUCTION**

Based on the review of the data on quality, safety and efficacy, the MHRA granted Medreich Plc a Marketing Authorisation for the medicinal product, Furosemide 20mg Tablets (PL 21880/0112), on 1st December 2010. The product is a prescription-only medicine (POM).

This is a simple, abridged, ‘informed consent’ application submitted according to Article 10(c) of EC Directive 2001/83 (as amended), cross-referencing the Marketing Authorisation for Furosemide 20mg Tablets (PL 20532/0039), licensed to Aurobindo Pharma Limited on 19th October 2005.

Furosemide 20mg Tablets are indicated for the:

- treatment of oedema associated with congestive heart failure, cirrhosis of the liver, renal disease including nephrotic syndrome
- treatment of peripheral oedema due to mild to moderate hypertension (alone, or in combination with other antihypertensive agents in the treatment of more severe cases)
- management of oliguria due to acute or chronic renal insufficiency

Furosemide belongs to the pharmacotherapeutic group, high-ceiling diuretics (ATC Code - C03C A01), a term used to denote a group of diuretics that have a distinctive action on renal tubular function. The peak diuresis is far greater than that observed with other agents.

The main site of action is the thick ascending loop of Henle where they inhibit electrolyte re-absorption. It increases renal blood flow without increasing the filtration rate. Such a change in renal haemodynamics reduces fluid and electrolyte re-absorption in the proximal tubule and may augment the initial diuretic response.

Furosemide is an inhibitor of carbonic anhydrase but this activity is too weak to contribute to a proximal diuresis except when massive doses are employed. Furosemide enhances the excretion of both calcium and magnesium to an extent approximately proportional to the increase in sodium excretion. Unlike the thiazides, high-ceiling diuretics do not increase calcium re-absorption in the distal tubule. The calciuric action of these agents is the basis for their use in symptomatic hypercalcaemia.

The pharmacovigilance system as described by the Marketing Authorisation Holder (MAH) fulfils the requirements and provides adequate evidence that the MAH has the services of a Qualified Person (QP) responsible for pharmacovigilance and has the necessary means for the notification of any adverse reaction suspected of occurring either in the Community or in a third country.

The MAH has provided adequate justification for not submitting an Environmental Risk Assessment (ERA). The therapeutic indications and posology of the proposed product are the same as that for the reference product. Marketing of Furosemide 20mg
Tablets is, therefore, not predicted to result in an overall increase in the environmental exposure concentrations of the active ingredient, furosemide.

No new data were submitted, nor was it necessary for this simple application, as the data are identical to that of the previously granted cross-reference product. As the cross-reference product was granted prior to the introduction of current legislation, no Public Assessment Report (PAR) was generated for it.
1. INTRODUCTION

This is a simple abridged application, submitted under Article 10c of Directive 2001/83/EC (as amended) for Furosemide 20mg Tablets. The proposed Marketing Authorisation Holder (MAH) is Medreich Plc.

The reference product is Furosemide 20mg Tablets (PL 20532/0039), authorised to Aurobindo Pharma Limited on 19th October 2005. The proposed and reference products are identical.

2. MARKETING AUTHORISATION APPLICATION FORM

2.1 Name(s)

The approved name of the product is Furosemide 20mg Tablets. The product has been named in line with current requirements and the product name is acceptable.

2.2 Strength, pharmaceutical form, route of administration, container and pack sizes

Each Furosemide 20mg Tablet contains 20 mg of the active ingredient, furosemide. The tablets are licensed for marketing in the following containers (full details are provided in the SmPC). The container closure systems and pack sizes are the same as those for the reference product:

i) Polypropylene tablet container with low-density polyethylene cap - pack sizes: 28, 56, 100, 250, 500 and 1000 tablets

ii) polyvinylchloride (PVC) / aluminium foil blister strips, packed into cardboard outer cartons - pack sizes: 28 and 56 tablets

The approved shelf-lives (5 years for the polypropylene container; 2 years for the blister packs) and storage conditions (‘Do not store above 25°C. Store in the original container. Keep the container tightly closed’ for the polypropylene container; and ‘Do not store above 25°C. Store in the original package’ for the blister packs) are identical to the details registered for the cross-reference product.

2.3 Legal status

POM - The product is available by supply through pharmacies, subject to a medical prescription.
2.4 Marketing Authorisation Holder / Contact Persons / Company
The proposed Marketing Authorisation Holder is ‘Medreich Plc, 9 Royal Parade, Kew Gardens, Surrey, TW9 3QD, United Kingdom’.

The Qualified Person (QP) responsible for pharmacovigilance was stated and their CV included.

2.5 Manufacturers
The proposed manufacturing sites are consistent with those registered for the cross-reference product and evidence of GMP compliance has been provided.

2.6 Qualitative and quantitative composition
The proposed composition is consistent with the details registered for the cross-reference product.

2.7 Manufacturing process
The proposed manufacturing process is consistent with the details registered for the cross-reference product and the maximum batch size is stated.

2.8 Finished product / shelf-life specification
The proposed finished product specification is identical to the details registered for the cross-reference product.

2.9 Drug substance specification
The proposed drug substance specification is consistent with the details registered for the cross-reference product.

2.10 TSE Compliance
The magnesium stearate is of vegetable origin. The only excipient used that contains material of animal or human origin is lactose monohydrate. The applicant has provided a declaration that milk used in the production of lactose monohydrate is sourced from healthy animals under the same conditions as that for human consumption. None of the excipients are sourced from genetically modified organisms.

3. EXPERT REPORT
A satisfactory quality overall summary has been prepared by an appropriately qualified expert. The CV of the expert was provided.

4. PRODUCT NAME & APPEARANCE
See 2.1 for details of the proposed product name. The appearance of the product (white, circular, flat bevelled-edge tablets with ‘F’-scoreline-‘20’ embossed on one face and plain on the reverse) is identical to that of the cross-reference product.

5. SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)
The approved SmPC is consistent with the details registered for the cross-reference product.
6. PATIENT INFORMATION LEAFLET (PIL) / LABELLING

PIL
The approved PIL is satisfactory and in line with the approved SmPC. It is consistent with the details registered for the cross-reference product.

PIL user testing has been accepted, based on bridging to the successful user-testing of the PIL for the reference product, Furosemide 20mg Tablets (PL 20532/0039). The text, content and layout of the proposed PIL are essentially identical to the approved PIL for the reference product. The bridging is accepted.

Labelling
Colour mock-ups of the labelling have been provided and are satisfactory. The approved labelling artwork complies with statutory requirements. In line with current legislation the applicant has included the name of the product in Braille on the outer packaging and has included sufficient space for a standard UK pharmacy dispensing label.

The MAH have committed to submitting mock-ups for currently unmarketed packs to the relevant regulatory authorities for approval before those packs are commercially marketed.

7. CONCLUSIONS
The grounds for this application are considered adequate. A Marketing Authorisation was, therefore, granted.
NON-Clinical Assessment

This is a simple, abridged, ‘informed consent’ application made under Article 10(c) of EC Directive 2001/83 (as amended).

No new non-clinical data have been supplied with this application and none are required for applications of this type. A non-clinical overview has been written by a suitably qualified person and is satisfactory. The CV of the non-clinical expert has been supplied.

The Marketing Authorisation Holder has provided adequate justification for not submitting an Environmental Risk Assessment (ERA).
CLINICAL ASSESSMENT

This is a simple, abridged, ‘informed consent’ application made under Article 10(c) of EC Directive 2001/83 (as amended), cross-referring to the Marketing Authorisation for Furosemide 20mg Tablets (PL 20532/0039).

No new clinical data have been supplied with the application, and none are required for applications of this type. A clinical overview has been written by a suitably qualified person and is satisfactory. The CV of the clinical expert has been supplied.
OVERALL CONCLUSION AND BENEFIT-RISK ASSESSMENT

QUALITY
The data for this application are consistent with those previously assessed for the cross-reference product and as such have been judged to be satisfactory.

NON-CLINICAL
No new non-clinical data were submitted and none are required for an application of this type.

EFFICACY
This application is considered identical to the previously granted licence for Furosemide 20mg Tablets (PL 20532/0039, Aurobindo Pharma Limited).

No new or unexpected safety concerns arise from this application.

PRODUCT LITERATURE
The approved SmPC and PIL are satisfactory and consistent with the details registered for the cross-reference product.

PIL user testing has been accepted, based on bridging to the successful user-testing of the PIL for the reference product, Furosemide 20mg Tablets (PL 20532/0039). The bridging is accepted.

Colour mock-ups of the labelling have been provided and are satisfactory. The approved labelling artwork complies with statutory requirements. The MAH have committed to submitting mock-ups for currently unmarketed packs to the relevant regulatory authorities for approval before those packs are commercially marketed.

BENEFIT-RISK ASSESSMENT
The quality of the product is acceptable and no new non-clinical or clinical safety concerns have been identified. The applicant's product is identical to the cross-reference product. The benefit: risk ratio is considered to be positive.
Furosemide 20mg Tablets

PL 21880/0112

STEPS TAKEN FOR ASSESSMENT

1. The MHRA received the Marketing Authorisation application on 9th September 2010
2. Following standard checks and communication with the applicant the MHRA considered the application valid on 29th September 2010
3. Following assessment of the application the MHRA requested further information relating to the quality dossier on 4th November 2010
4. The applicant responded to the MHRA’s requests, providing further information for the quality sections on 24th November 2010
5. The application was determined on 1st December 2010
Furosemide 20mg Tablets

PL 21880/0112

STEPS TAKEN AFTER AUTHORISATION

Not applicable
SUMMARY OF PRODUCT CHARACTERISTICS

The UK Summary of Product Characteristics (SmPC) for Furosemide 20mg Tablets (PL 21880/00112) is as follows:

1 NAME OF THE MEDICINAL PRODUCT
Furosemide 20mg Tablets.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION
Each tablet contains 20mg furosemide.
For excipients, see 6.1

3 PHARMACEUTICAL FORM
Tablet.
Appearance: A white, circular, flat bevelled edge tablet with ‘F’ scoreline 20’ embossed on one face and plain on the reverse.

4 CLINICAL PARTICULARS
4.1 Therapeutic indications
In the treatment of oedema associated with congestive heart failure, cirrhosis of the liver, renal disease including nephrotic syndrome.

In the treatment of peripheral oedema due to mild to moderate hypertension (alone, or in combination with other antihypertensive agents in the treatment of more severe cases).

Management of oliguria due to acute or chronic renal insufficiency.

4.2 Posology and method of administration
Adults: The usual initial daily dose is 40mg. This may require adjustment until the effective dose is achieved. In mild cases 20mg daily or 40mg on alternate days may be sufficient, whereas in cases of resistant oedema daily doses of 80mg and above may be used.

In patients with chronic renal insufficiency, an initial daily dose of 250mg is employed. If a satisfactory diuresis is not produced then the dose may be increased in steps of 250mg at four to six hourly intervals up to a maximum daily dose of 1,500 mg in 24 hours. In exceptional cases up to 2,000 mg in 24 hours may be given.

Children: The oral dose for children ranges from 1-3mg/kg body weight daily, up to a maximum total dose of 40mg per day.

Elderly: The usual adult dose, but caution is advised as furosemide is excreted more slowly in the elderly.

Method of administration: Oral – the tablets should be swallowed with water.

4.3 Contraindications
Furosemide is contra-indicated in the presence of anuria, electrolyte deficiency, precoma associated with hepatic cirrhosis, digitalis intoxication, porphyria and hypersensitivity to furosemide or sulphonamides.

4.4 Special warnings and precautions for use
Where indicated, steps should be taken to correct hypotension or hypovolaemia before commencing therapy. Regular monitoring of fluid and electrolyte balance is recommended.

Use with caution in patients with impaired hepatic or renal function, diabetes mellitus or adrenal disease.
Use with care in elderly patients or those with prostatic hypertrophy or impairment of micturition.

Latent diabetes may become manifest or the insulin requirements of diabetic patients may increase.

Hypotension may occur if ACE inhibitors are added to furosemide therapy. The dose of furosemide should be reduced or the drug stopped before initiating the ACE inhibitor.

Use with caution in patients with a history of gout. Discontinue furosemide if bone marrow depression occurs.

This product contains lactose. Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.

4.5 Interaction with other medicinal products and other forms of interaction

Furosemide may enhance the toxicity of cardiac glycosides by electrolyte disturbance particularly potassium and magnesium.

The action of antihypertensive agents such as methyldopa may be enhanced by furosemide. The nephrotoxic effect of cephaloridine and the aminoglycoside antibiotics may be increased by furosemide.

The action of diuretics such as furosemide may be antagonised by certain non-steroidal anti-inflammatory agents.

The renal clearance of lithium is decreased by furosemide, resulting in increased and possibly toxic serum levels. Concomitant administration should be avoided unless plasma levels can be monitored.

Concurrent administration of glucocorticoids may cause sodium retention and exacerbate potassium loss.

Furosemide decreases the effects of some drugs (e.g. antidiabetics and pressor amines) and may potentiate the effects of others (e.g. salicylates, theophylline, and curare type muscle relaxants).

Resultant hypokalaemia may potentiate cardiac toxicity of certain drugs such as antihistamines and antiarrhythmics. It may also antagonise the action of antiarrhythmics such as lidocaine, mexiletine and tocainide.

4.6 Pregnancy and lactation

Furosemide has been given after the first trimester of pregnancy for oedema, hypertension and toxaemia of pregnancy without causing foetal or new-born adverse effects. However, it should only be given during pregnancy if strictly indicated and for short-term treatment.

As it may inhibit lactation and passes into breast milk, furosemide should be used with caution in nursing mothers.

4.7 Effects on ability to drive and use machines

Reduced mental alertness and rarely dizziness and blurred vision have been reported. Patients so affected should not drive or operate machines.

4.8 Undesirable effects

Furosemide is generally well tolerated. Fluid and electrolyte imbalance is the most common side effect. Uncommonly nausea, diarrhoea, blurred vision, dizziness, headache, pancreatitis, photosensitivity, vasculitis and interstitial nephritis have occurred very rarely. The incidence of allergic reactions such as skin rashes is very low, but when these occur treatment should be withdrawn.
A transient rise in creatinine may occur as may hypotension and liver dysfunction. Muscle spasm and paraesthesia have also been reported. Hyperuricaemia may be induced and precipitate gout in some patients.

Temporary increase in plasma cholesterol and triglyceride concentrations may occur. Latent diabetes may become manifest and the insulin requirements of diabetic patients may increase.

Bone marrow depression is a rare complication and treatment should be withdrawn. The haemopoietic status should therefore be regularly monitored.

Calcium depletion may occur and nephrocalcinosis has been reported in premature infants.

Tinnitus and deafness have occurred, usually with large parenteral doses and rapid administration and in renal impairment.

4.9 Overdose
In cases of overdosage there is a danger of dehydration and electrolyte depletion due to excessive diuresis. Treatment should be aimed at fluid replacement and correction of electrolyte imbalance. Gastric lavage may be useful if ingestion is recent.

5 PHARMACOLOGICAL PROPERTIES
5.1 Pharmacodynamic properties
Furosemide ATC Code: C03CA01

Furosemide is one of the high ceiling diuretics, a term used to denote a group of diuretics that have a distinctive action on renal tubular function. The peak diuresis is far greater than that observed with other agents.

The main site of action is the thick ascending loop of Henle where they inhibit electrolyte re-absorption. It increases renal blood flow without increasing the filtration rate. Such a change in renal haemodynamics reduces fluid and electrolyte re-absorption in the proximal tubule and may augment the initial diuretic response.

Furosemide is an inhibitor of carbonic anhydrase but this activity is too weak to contribute to a proximal diuresis except when massive doses are employed. Furosemide enhances the excretion of both calcium and magnesium to an extent approximately proportional to the increase in sodium excretion. Unlike the thiazides, high ceiling diuretics do not increase calcium re-absorption in the distal tubule. The calciuric action of these agents is the basis for their use in symptomatic hypercalcaemia.

5.2 Pharmacokinetic properties
Furosemide is incompletely but fairly rapidly absorbed from the gastrointestinal tract. Bioavailability is about 65%. It has a biphasic half-life in plasma with a terminal elimination phase up to about 2 hours but this is prolonged in neonates, and in patients with hepatic and renal insufficiency.

It is extensively bound to plasma proteins but is rapidly secreted by the organic acid transport system of the proximal tubule. In this manner it gains access to the tubular fluid and eventually to its site of action more distally.

It is mainly excreted in the urine largely unchanged, but also in the form of glucuronide and free amine metabolites. Variable amounts are also excreted in the bile. Furosemide crosses the placental barrier and is excreted in milk. Non renal elimination is considerably increased in renal failure. The clearance of furosemide is not increased by haemodialysis.

5.3 Preclinical safety data
Not relevant
6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients
Lactose monohydrate
Magnesium stearate (E470b)
Sodium starch glycollate
Maize starch.
Starch paste 15%

6.2 Incompatibilities
Not Applicable

6.3 Shelf life
Tablet container: 5 Years
Blister: 2 Years

6.4 Special precautions for storage
Tablet containers: Do not store above 25°C. Store in the original container. Keep the container tightly closed.
Blister packs: Do not store above 25°C. Store in the original package.

6.5 Nature and contents of container
Tablet container and cap (polypropylene container with low density polyethylene cap)
Pack sizes: 28, 56, 100, 250, 500 and 1000 tablets.
Blister (250 (μm white opaque PVC and 20 (μm hard temper aluminium foil).
Pack sizes: 28 and 56 tablets.

6.6 Special precautions for disposal
Not applicable

7 MARKETING AUTHORISATION HOLDER
Medreich Plc,
9 Royal Parade,
Kew Gardens,
Surrey,
TW9 3QD,
United Kingdom

8 MARKETING AUTHORISATION NUMBER(S)
PL 21880/0112

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION
01/12/2010

10 DATE OF REVISION OF THE TEXT
01/12/2010
UKPAR Furosemide 20mg Tablets

PATIENT INFORMATION LEAFLET

PACKAGE LEAFLET: INFORMATION FOR THE USER

Furosemide 20mg Tablets
(furosemide)

Read all of this leaflet carefully before you start taking this medicine.
- 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. Do not pass it on to others.
- It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:
1. What Furosemide Tablets are and what are they used for
2. Before you take Furosemide Tablets
3. How to take Furosemide Tablets
4. Possible side effects
5. How to store Furosemide Tablets
6. Further information

1. WHAT FUROSEMIDE TABLETS ARE AND WHAT ARE THEY USED FOR

Furosemide Tablets contain furosemide as the active ingredient. This belongs to a group of medicines called diuretics (also called water tablets). Furosemide Tablets are used to treat oedema (fluid retention) caused by heart failure, mild to moderate hypertension (high blood pressure) and certain liver and kidney disorders. They are also used to manage a condition called oliguria where the body produces an abnormally small amount of urine, due to kidney disease.

2. BEFORE YOU TAKE FUROSEMIDE TABLETS

Do not take Furosemide Tablets if you have:
- an allergy (hypersensitivity) to furosemide or any of the other ingredients in the product (see Section 6 and end of Section 2)
- an allergy to any other diuretics or sulphonamides (e.g. sulphamethoxazole)
- absence of urine production
- an electrolyte deficiency (various ions, such as sodium or chloride, required by your body)
- precoma associated with liver disease
- taken a heart medicine overdose (digitalis intoxication)
- porphyria, a metabolic disorder.

Take special care with Furosemide Tablets if you
- have low blood pressure or an abnormally increased volume of blood. Your fluid and electrolyte balance should be regularly monitored.
- suffer from gout or diabetes
- have kidney/adrenal or liver problems
- have a prostate problem or difficulty in passing urine
- are elderly.

Taking other medicines
Please inform your doctor if you are taking or have recently taken any other medicines, including those obtained without a prescription.
In particular, tell your doctor if you are taking:
- medicines used to treat high blood pressure, such as methyldopa.
- antibiotics such as cephaloridine.
- non-steroidal anti-inflammatory drugs (NSAIDs) such as ibuprofen.
- lithium, a treatment for depression.
- medicines used to treat heart conditions such as digoxin, lidocaine, mexiletine and tocolidine.
- medicines used for diabetes.
- glucocorticoids involved in carbohydrate, fat and protein metabolism.
- salicylates, for example aspirin.
- theophyllines which are used to help breathing.
- muscle relaxants and antihistamines.
- ACE inhibitors (low blood pressure may occur if ACE inhibitors are added to furosemide therapy. The dose of furosemide should be reduced or the drug stopped before initiating the ACE inhibitor).

Pregnancy and breast-feeding
Furosemide Tablets should only be taken during pregnancy if considered essential by your doctor, and only for short-term treatment. Furosemide passes into breast milk, so inform your doctor if you are breast-feeding.
Ask your doctor for advice before taking any medicine.

Driving and using machines
As this medicine may reduce mental alertness and cause dizziness, you should not drive or operate machinery until you know how the drug affects you.

Important information about some of the ingredients of Furosemide Tablets
Lactose - if you know you have an intolerance to some sugars, contact your doctor before taking this medicine.
3. HOW TO TAKE FUREOSEMIDE TABLETS

For Oral Use Only.
Furosemide Tablets should be swallowed with a drink of water.
Always take the tablets exactly as your doctor has told you. The pharmacist’s label should tell you how much to take and how often.

Adults and the Elderly: The usual dose is 20 - 40mg daily. If you suffer from long term kidney trouble, your doctor may prescribe a starting dose of 250mg furosemide per day which may be increased to 250mg every 4 to 6 hours, up to a maximum of 1500mg per day.

Children: The dose is worked out according to the child’s weight. A dose of 1 - 3mg for each kilogram of the child’s body weight should be given daily. Do not exceed 40mg per day.

If you take more Furosemide Tablets than you should
If you or anyone else has swallowed a lot of the tablets, contact your doctor or nearest hospital casualty department immediately.

If you forget to take Furosemide Tablets
If you miss a dose, take another as soon as you remember and carry on as before (do not take a double dose to make up for a forgotten dose). You should continue to take these tablets for as long as your doctor tells you to.

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, Furosemide Tablets can cause side effects, although not everyone gets them.
Skin rash or itching suggest an allergic reaction, in which case you should stop taking the tablets immediately and inform your doctor.

Furosemide Tablets may cause other unwanted effects including:
• hearing difficulty or ringing in the ears, dizziness, stomach upset, nausea, diarrhoea, blurred vision, headache, abdominal pain, inflammation of the pancreas, over-sensitivity to light, muscle cramps, pins and needles, gout, diabetes, kidney or liver disorders, low blood pressure, inflammation of blood vessels.

The tablets may occasionally alter the composition of your blood, and your doctor may want to do some blood tests from time to time. If you are to undergo a blood test, remember to tell the doctor of your treatment with furosemide.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE FUREOSEMIDE TABLETS

Keep all medicines out of the reach and sight of children.
Do not store above 25°C.
Store in the original package/container and keep tightly closed.
This medicine should not be used after the expiry date printed on the pack.
Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Furosemide Tablets contain
The active substance is furosemide, 20mg.
The other ingredients are lactose, magnesium stearate (E572), sodium starch glycollate maize starch and starch paste 15% (see Section 2 Important information about some of the ingredients of Furosemide Tablets’).

What Furosemide Tablets look like and contents of the pack
20mg tablets - white circular flat bevelled edged tablet with ‘F scoreline 20’ embossed on one face and plain on the reverse.

Pack sizes (not all may be marketed):
20mg - 28, 56, 100, 250, 500, 1000 tablets.

PL No.: 21880/0112

Manufacturer
Milpharm Limited
Ares, Odyssey Business Park
West End Road
South Ruislip, HA4 6QD
United Kingdom

This leaflet was last approved in November 2010

POM
LABELLING

Carton for blisters

**Furosemide 20 mg Tablets**

Each tablet contains:
Furosemide 20 mg
Also contains: Lactose Monohydrate, see the leaflet for further information
- Read the package leaflet before use.
- For oral administration.
- Use as directed by the physician.
- Do not store above 25°C.
- Store in the original package.

**KEEP OUT OF THE REACH AND SIGHT OF CHILDREN**

**MEDREICH**

83 mm

**Furosemide**

**#20 mg**

**Tablets**