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240 mm

Spiromide®

20mg, 40mg Tablets

(Spironolactone BP and Furosemide Ph. Eur.)

Composition:
SPIROMIDE20: Each tablet containing:
Spironolactone (B.P) …….50 mg
Furosemide (Ph. Eur.) ……20 mg

SPIROMIDE 40: Each tablet containing:
Spironolactone (B.P) …….50 mg
Furosemide (Ph. Eur.) ……40 mg

Read all of this leaflet carefully before you start taking 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, pharmacist, or nurse.
- 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, pharmacist, or nurse. This includes any possible side effects not listed in this leaflet.

What is in this leaflet

1. What Spiromide is and what it is used for
Spiromide are Diuretics; High-ceiling diuretics and potassium-sparing agents
Pharmacodynamic properties Furosemide: Furosemide is a diuretic acting on the Loop of Henle. Spironolactone: Spironolactone is a competitive inhibitor of aldosterone.
Spiromide contains a short-acting diuretic and a long-acting aldosterone antagonist. It is indicated in the treatment of resistant oedema where this is associated with secondary hyperaldosteronism; conditions include chronic congestive cardiac failure and hepatic cirrhosis.
Treatment with Spironolactone & Furosemide combination should be reserved for cases refractory to a diuretic alone at conventional doses. This fixed ratio combination should only be used if titration with the component drugs separately indicates that this product is appropriate.
The use of Spironolactone & Furosemide combination in the management of essential hypertension should be restricted to patients with demonstrated hyperaldosteronism. It is recommended that in these patients also, this combination should only be used if titration with the component drugs separately indicates that this product is appropriate.

2. What you need to know before you take Spiromide
Do not take Spiromide
Patients with hypovolemia or dehydration (with or without accompanying hypotension). Patients with an impaired renal function and a creatinine clearance below 30ml/min per 1.73 m2 body surface area, 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, hyperkalaemia, severe Hypokalaemia severe hyponatremia, Addison's disease, during pregnancy and breast-feeding women.
Hypersensitivity to furosemide, spironolactone, sulphonamides or sulphonamide derivatives, or any of the excipients of Spironolactone, furosemide.
Warnings and precautions:
Spironolactone may cause vocal changes. In determining whether to initiate treatment with Spiromide, special attention must be given to this possibility in patients whose voice is particularly important for their work (e.g., actors, singers, teachers).
Urinary output must be secured. Patients with partial obstruction of urinary outflow, for example patients with prostatic hypertrophy or impairment of micturition have an increased risk of developing acute retention and require careful monitoring.
Where indicated, steps should be taken to correct hypotension or hypovolemia before commencing therapy. Particularly careful monitoring is necessary in:
- patients with hypotension.
- patients who are at risk from a pronounced fall in blood pressure.
- patients where latent diabetes may become manifest or the insulin requirements of diabetic patients may increase.
- patients with gout, patients with hepatic cirrhosis together with impaired renal function.
- patients with hypoproteinemia, e.g. associated with nephrotic syndrome (the effect of furosemide may be weakened and its ototoxicity potentiated). Cautious dose titration is 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.

Administration of Spiromide should be avoided in the presence of a raised serum potassium. Concomitant administration of triamterene, amiloride, potassium supplements or non-steroidal anti-inflammatory drugs is not recommended as hyperkalaemia may result. Concomitant use of medicinal products known to cause hyperkalaemia with spironolactone may result in severe hyperkalaemia.
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. Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.
DRUG INTERACTIONS
Absorption of spironolactone is increased if Furosemide and Spironolactone is taken together with food. The clinical relevance of this interaction is unknown.The dosage of concurrently administered cardiac glycosides, diuretics, antihypertensive 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 and Spironolactone combination. A marked fall in blood pressure and deterioration in renal function may be seen when ACE inhibitors or angiotensin II receptor antagonists are added to furosemide therapy, or their dose level increased. When combination of Furosemide and Spironolactone is taken in combination with potassium salts, with drugs which reduce potassium excretion, with non-steroidal anti-inflammatory drugs or with ACE inhibitors, an increase in serum potassium concentration and hyperkalaemia may occur. The toxic effects of nephrotoxic drugs may be increased by concomitant administration of potent diuretics such as furosemide. In common with other diuretics, serum lithium levels may be increased when lithium is given concomitantly with combination of Furosemide and Spironolactone, resulting in increased lithium toxicity, including increased risk of cardiotoxic and neurotoxic effects of lithium. 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 for use regarding increased mortality in elderly patients with dementia concomitantly receiving risperidone. Levothyroxine: High doses of furosemide may inhibit binding of thyroid hormones to carrier proteins and thereby lead to an initial transient increase in free thyroid hormones, followed by an overall decrease in total thyroid hormone levels. Certain non-steroidal anti-inflammatory agents (e.g. indomethacin, acetylsalicylic acid) may attenuate the action of Furosemide and Spironolactone and may cause acute renal failure in cases of pre-existing hypovolemia or dehydration. Salicylic toxicity may be increased by Furosemide and Spironolactone combination. Furosemide and Spironolactone may sometimes attenuate the effects of other drugs and sometimes potentiate them. Furosemide and Spironolactone combination may potentiate the ototoxicity of aminoglycosides and other ototoxic drugs. Since this may lead to irreversible damage, these drugs must only be used with Furosemide and Spironolactone combination if there are compelling medical reasons. There is a risk of ototoxic effects if cisplatin and furosemide are given concomitantly. In addition, nephrotoxicity of cisplatin may be enhanced if furosemide is not given in low doses and with positive fluid balance when used to achieve forced diuresis during cisplatin treatment. Spironolactone may cause raised digoxin levels. 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). Attenuation of the effect of Furosemide and Spironolactone combination may occur following concurrent administration of phenytoin. Concomitant administration of carbamazepine or aminoglutethimide may increase the risk of hyponatremia. Corticosteroids administered concurrently may cause sodium retention. Both spironolactone and carbenoloxone may impair the action of the other substance. Probenecid, methotrexate and other drugs which, like furosemide, undergo significant renal tubular secretion may reduce the effect of Furosemide and Spironolactone combination. Impairment of renal function may develop in patients receiving concurrent treatment with furosemide and high doses of certain cephalosporins. Concomitant use of ciclosporin and furosemide is associated with increased risk of gouty arthritis. Cholestyramine: Hyperkalaemia could occur in the context of hyperchloremic metabolic acidosis in patients given Furosemide and Spironolactone combination concurrently with cholestyramine. In addition to other medicinal products known to cause hyperkalaemia, concomitant use of trimethoprim/sulfamethoxazole (co-trimoxazole) with spironolactone

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may result in clinically relevant hyperkalaemia.
Pregnancy and breast-feeding:
Pregnancy: Results of animal work, in general, show no hazardous effect of furosemide in pregnancy. There is clinical evidence of safety of the drug in the third trimester of human pregnancy; however, furosemide crosses the placental barrier. Spironolactone or its metabolites may cross the placental barrier. Animal studies have shown feminization of the genitalia in male offspring. Antiandrogenic effects have been reported in humans with the risk of ambiguous external genitalia in male newborns. Furosemide and Spironolactone combination must not be used in pregnancy unless there are compelling medical reasons. Treatment during pregnancy requires monitoring of foetal growth.
Lactation: Furosemide passes into breast milk and may inhibit lactation. Canerone, a metabolite of spironolactone, appears in breast milk and Furosemide and Spironolactone combination must therefore not be used in breast-feeding mothers.
Driving and using machines
Reduced mental alertness may impair the ability to drive or operate dangerous machinery. This applies especially at the commencement of treatment.
3. How to take Spiromide
For oral administration. The dose must be the lowest that is sufficient to achieve the desired effect. Adults: 1-4 Tablets daily. Children: The product is not suitable for use in children.
Elderly: Furosemide and Spironolactone may both be excreted more slowly in the elderly.
Method of administration: Tablets are best taken at breakfast and/or lunch with a generous amount of liquid (approx. 1 glass). An evening dose is not recommended, especially during initial treatment, because of the increased nocturnal output of urine to be expected in such case
If you take more Spiromide than you should
The clinical picture in acute or chronic overdose depends primarily on the extent and consequences of electrolyte and fluid loss, e.g. hypovolemia, dehydration, hemoconcentration, cardiac arrhythmias due to excessive diuresis. Treatment should therefore be aimed at fluid replacement and correction of the electrolyte imbalance. If ingestion has only just taken place, attempts may be made to limit further systemic absorption of the active ingredient by measures such as gastric lavage or those designated to reduce absorption (e.g. activated charcoal).
If you forget to take Spiromide
If you forget to take a dose of spironolactone, take it as soon as you remember, unless it's after 6pm. In this case, skip the missed dose and take your next dose at the usual time the next day.
Do not take 2 doses to make up for a forgotten dose.
If you often forget doses, it may help to set an alarm to remind you. You can also ask your pharmacist for advice on other ways to help you remember to take your medicine.
If you stop taking Spiromide
Talk to your doctor if you want to stop taking spiromide. If you stop it too soon, your condition may get worse.
4. Possible side effects
Adverse reactions are ranked by System organ class and then by frequency with the most frequent first, using the following convention: 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). Within each frequency grouping, adverse reactions are ranked in order of decreasing seriousness. Furosemide is generally well tolerated.
Blood and lymphatic system disorders
Frequency not known: Bone marrow depression has been reported as a rare complication and necessitates withdrawal of treatment.
Occasionally, thrombocytopenia may occur. In rare cases, leucopenia and, in isolated cases, agranulocytosis, aplastic anemia or haemolytic anemia may develop. Eosinophilia is rare.
Nervous system disorders
Frequency not known: Paraesthesia may occur.
Hepatic encephalopathy in patients with hepatocellular insufficiency may occur.
Dizziness, fainting and loss of consciousness (caused by symptomatic hypotension), headache.
Renal and urinary disorders
Frequency not known: Serum calcium levels may be reduced; in very rare cases tetany has been observed. Nephrocalcinosis / Nephrolithiasis has been reported in premature infants.
Ear and labyrinth disorders
Frequency not known: Hearing disorders and tinnitus, although usually transitory, may occur in rare cases, particularly in patients with renal failure, hypoproteinemia (e.g. in nephrotic syndrome) and/or when intravenous furosemide has been given too rapidly.
Frequency uncommon:
Cases of deafness, sometimes irreversible have been reported after oral or IV administration of furosemide.
Vascular disorders
Frequency not known: 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.
Hepato-biliary disorders
Frequency not known: In isolated cases, intrahepatic cholestasis, an increase in liver transaminases or acute pancreatitis may develop.
Skin and subcutaneous tissue disorders.
Frequency not known: The incidence of allergic reactions, such as skin rashes, photosensitivity, vasculitis, fever or interstitial nephritis, is very low, but when these occur treatment should be withdrawn. Skin and mucous membrane reactions may occasionally occur, e.g. itching, urticaria, other rashes or bullous lesions, erythema multiforme, bullous pemphigoid, Stevens-Johnson syndrome, toxic epidermal necrolysis, exfoliative dermatitis, purpura, AGEP (acute generalized exanthematous pustulosis) and DRESS (Drug rash with eosinophilia and systemic symptoms), lichenoid reactions.
Metabolism and nutrition disorders
Frequency not known: As with other diuretics, electrolytes and water balance may be disturbed as a result of diuresis after prolonged therapy.
Immune system disorders
Frequency not known: Severe anaphylactic or anaphylactoid reactions (e.g. with shock) occur rarely.
Exacerbation or activation of systemic lupus erythematosus.
Gastro-intestinal disorders
Frequency not known: Side-effects of a minor nature such as nausea, malaise or gastric upset (vomiting or diarrhoea) may occur but are not usually severe enough to necessitate withdrawal of treatment.
Reproductive system and breast disorders
Frequency not known: Because of its chemical similarity to the sex hormones, spironolactone may make the nipples more sensitive to touch. Dose dependent mastodynia and reversible gynecomastia may occur in both sexes. If furosemide is administered to premature infants during the first weeks of life, it may increase the risk of persistence of patent ductus arteriosus.
Respiration, thoracic and mediastinal disorders
Frequency not known: Rarely, spironolactone may cause vocal changes in the form of hoarseness and (in women), deepening of the voice or (in men) increase in pitch. In some patients these vocal changes persist even after Furosemide and Spironolactone combination has been discontinued.
Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorization 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 at pv@searlecompany.com

5. Presentation
SPIROMIDE: Boxes of 20 tablets (2 x 10's blister Strips)
SPIROMIDE 40: Boxes of 30 tablets (3 x 10's blister Strips)

6. Instructions
To be sold on the prescription of a registered medical practitioner only.
Do not store and transport above 30°C.
Protect from sunlight, moisture and heat.
Keep all medicines out of sight & reach of children.
Product contains Lactose.

SEARLE
Manufactured by:
The Searle Company Limited,
F-319, S.I.T.E., Karachi-Pakistan.
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RAW/Pil-SPI.T/824-000(001)

THE *SEARLE* COMPANY LIMITED

APPROVED

Product Name: Spiromide
Artwork: Leaflet (RAWANDA)
Creation Date: 29-8-2024
Revision Date: ----------
Revision Number: ----------
Size:(120x240)mm
Color: Pantone 293C

DEPARTMENT	NAME	SIGNATURE
Designed by		
Marketing		
Medical		
Regulatory		
Business Development		
QA Artwork Section		
Quality Control		
Production		
Research & Development		

Item Code	Artwork Version	Description of change in Artwork	Change Control #/NPIF	Date of Approval