Pentasa® Suppositories 1 g

Note: Other use or other dosages than stated below can be prescribed by your physician. In such cases the physician's prescription should be followed.

Pharmaceutical form:
Suppositories

Declaration of content:
1 suppository contains 1 g of mesalazine as the active ingredient.
Povidone, macrogol 6000, magnesium stearate and talc are added as excipients.

Mode of action:
Pentasa® suppositories are effective in the treatment of chronic inflammatory bowel disease.

Therapeutic indications:
Chronic inflammatory bowel disease located to the rectum (ulcerative proctitis).

Contraindications:
Hypersensitivity to mesalazine, any other component of the product, or salicylates. Severe liver or renal impairment.

Special warnings and precautions for use:
Caution is recommended when treating patients allergic to sulphasalazine (risk of allergy to salicylates).

Caution is recommended in patients with impaired liver function. The drug is not recommended for use in patients with renal impairment. The renal function should be monitored regularly (e.g. serum creatinine), especially during the initial phase of treatment. Mesalazine induced nephrotoxicity should be suspected in patients developing renal dysfunction during treatment.

Mesalazine-induced cardiac hypersensitivity reactions (myo- and pericarditis) have been reported rarely. Serious blood dyscrasias have been reported very rarely with mesalazine. Treatment should be discontinued on suspicion or evidence of these adverse reactions.

Care should be taken in children below 2 years.

Interaction with other medicaments and other forms of interaction
There are no data on interactions between Pentasa® and other drugs.

Pregnancy and lactation
Pentasa® should be used with caution during pregnancy and lactation and only if the potential benefits outweigh the possible hazards in the opinion of the physician.

Mesalazine is known to cross the placental barrier, but the limited data available on the use of this compound in pregnant women do not allow assessment of possible adverse effects. No teratogenic effects have been observed in animal studies.

Mesalazine is excreted in breast milk. The concentration is lower than in maternal blood, whereas the metabolite - acetyl-mesalazine - appears in similar or increased concentrations. No adverse effects in suckling babies of mothers treated with Pentasa® have been reported, but the data are very limited.

Effect on ability to drive and use machines:
None.

Dosage:
Adults: 1 g (1 suppository) 1-2 times daily.

Instructions for use:
1. A visit to the toilet is recommended before inserting a suppository.
2. Open the foil bag at the tear mark.
3. Place one of the enclosed finger protectors on the insertion finger. The suppository is inserted in the rectum until resistance is felt and disappears again.
4. In order to facilitate the administration, the suppository can be moistured with water or moisture cream.
5. If the suppository is discharged within the first 10 minutes, another can be inserted.
6. Dispose of the foil and the used finger protector.

Overdose:
Acute experience in animals: Single oral doses of mesalazine up to 5 g/kg in pigs or a single intravenous dose of mesalazine at 920 mg/kg in rats were not lethal.

Human experience: No cases of overdose have been reported.

Management of overdose in man: Symptomatic treatment at hospital. Close monitoring of renal function.

Undesirable effects:
The most frequent adverse reactions seen in clinical trials are diarrhoea (3%), nausea (3%), abdominal pain (3%), headache (3%), vomiting (1%), and rash (1 %).

Hypersensitivity reactions and drug fever may occasionally occur.

Following rectal administration local reactions such as pruritus, rectal discomfort and urge may occur.

Frequency of adverse effects, based on clinical trials and reports from post-marketing surveillance:

Common (≥1% and <10%)	General:	headache
	Gastro-intestinal:	diarrhoea, abdominal pain, nausea, vomiting
	Skin disorders:	rash (incl. urticaria, erythematous rash)
Rare (≥0.01% and <0.1%)	Cardiac disorders:	myo*- and pericarditis*
	Gastro-intestinal:	increased amylase, pancreatitis*
Very rare (<0.01%)	Skin disorders:	reversible alopecia
	Collagen disorders:	Isolated reports of lupus erythematosus-like reactions
	Liver:	increased liver enzymes and bilirubin, hepatotoxicity (incl. hepatitis*, cirrhosis, hepatic failure)
	Urogenital:	abnormal renal function (incl. interstitial nephritis*, nephrotic syndrome)
	Respiratory:	allergic lung reactions (incl. dyspnoea, coughing, allergic alveolitis, pulmonary eosinophilia, pulmonary infiltration)
	Musculo-skeletal:	myalgia, arthralgia
	Blood disorders:	eosinophilia (as part of an allergic reaction), anaemia, aplastic anaemia, leucopenia (incl. granulocytopenia), thrombocytopenia, agranulocytosis, pancytopenia

(*) The mechanism of mesalazine-induced myo- and pericarditis, pancreatitis, nephritis and hepatitis is unknown, but it might be of allergic origin.

It is important to note that several of these disorders can also be attributed to the inflammatory bowel disease itself.

Incompatibilities
None known.

Storage:
Storage at room temperature (15-25 °C) in the original package.

Shelf life:
3 years

Expiry date:
See date stamp on the package.
Must not be used after the expiry date.

Manufactured by:
Pharbil Pharma GmbH
Bielefeld, Germany

For:
FERRING GmbH
Kiel, Germany

Date of the latest revision of the package insert:
April 2007

Medigrafik A/S

MEDIGRAFIK A/S · WALGERHOLM 20-22 · DK-3500 VÆRLØSE · DENMARK
Tel. +45 44 65 56 00 · Fax +45 44 65 67 03 · E-mail prepress@medigrafik.com
www.cerbo.com

Article No.:	2009050630	Country:	HK, MY, SG
Description:	Pentasa suppositories		
Pharma Code:	353		
Printers proof No.:	1	Date:	14-06-2007
Order No.:	143178		
Format:	SMP 200 x 200 mm		
Colours:	Black, Magenta (DO NOT PRINT)		
Replaces:	None		
Material specification No.:	E-MS-3004		

____ Approved for printing

Date: _____ Sign._____