

BLISS GVS PHARMA LTD.		
Product: Melanez 500 1g Supp.	Market: Malaysia	Size: (L x H) 130 x 340 mm
Component : Leaflet	Artwork code: 13009731	Pack Size: -----
Color Shades: ■ Black		Mfg Location: BGPL
Barcode: NA	Substrate: 40 gsm Bible Paper	
Reason for Issue: New Artwork		Date of Initiation: 30-07-2022
		Supercede Code : N.A.
Path	D:\H Drive\INT5\MELANEZ 500MG\Malasia /MELANEZ 1G -500 leaflet new.cdr	ZMARF No.: MARF0002731

MELANEZ SUPPOSITORIES 500 mg
Mesalazine 500 mg

MELANEZ SUPPOSITORIES 1G
Mesalazine 1g

Product Description

Melanez Suppositories 500 mg: Off white to light brown opaque bullet shaped suppository. (Length: 26.7 mm, Width: 8.5 ± 0.3 mm)
Melanez Suppositories 1 g: Off white to light brown opaque bullet shaped suppository. (Length: 33.0 mm, Width: 10.4 ± 0.3 mm)

Composition

Melanez Suppositories 500mg
Each suppository contains Mesalazine 500mg
Melanez Suppositories 1g
Each suppositories contains Mesalazine 1g

Pharmacodynamics

Pharmacotherapeutic group: intestinal anti-inflammatory agents; aminosalicyclic aid and similar agents
ATC code: A07EC02

Mechanism action

The mechanism of the anti-inflammatory action is unknown. The results of in vitro studies indicate that inhibition of lipoxxygenase may play a role.
Effects on prostaglandin concentrations in the intestinal mucosa have been demonstrated. Mesalazine (5-Aminosalicyclic acid/ 5-ASA) may also function as a radical scavenger of reactive oxygen compounds.

Pharmacodynamic effects

On reaching the intestinal lumen, rectally administered mesalazine has largely local effects on the intestinal mucosa and submucosal tissue.

Pharmacokinetics

General consideration of mesalazine

Absorption

Mesalazine absorption is highest in proximal gut regions and lowest in distal gut areas.

Biostransformation

Mesalazine is metabolized both pre-systematically by the intestinal mucosa and in the liver to the pharmacologically inactive N-acetyl-5-aminosalicylic acid (N-Ac-5-ASA). The acetylation seems to be independent of the acetylator phenotype of the patient. Some acetylation also occurs through the action of colonic bacteria. Protein binding of mesalazine and N-Ac-5-ASA is 43% and 78%, respectively.

Elimination

Mesalazine and its metabolite N-Ac-5-ASA are eliminated via the faeces (major part), renally (varies between 20 and 50%, dependent on kind of application, pharmaceutical preparation and route of mesalazine release, respectively) and biliary (minor part). Renal excretion predominantly occurs as N-Ac-5-ASA. About 1% of total orally administered mesalazine dose is excreted into the breast milk mainly as N-Ac-5-ASA.

Melanez Suppositories 500mg specific:

Distribution

Based on published data, technetium-labelled Melanez Suppositories 500mg showed peak spread of the suppository that had melted due to body temperature after 2-3 hours. The spread was limited primarily to the rectum and rectosigmoid junction. Melanez Suppositories 500 mg are thus particularly suitable for treating proctitis (ulcerative colitis of the rectum).

Absorption

After both a single administration and after several weeks of long-term treatment with 500 mg mesalazine three times daily as Melanez Suppositories, peak plasma concentrations of 5-ASA were in the range of 0.1 to 1.0 ug/ml, those of the main metabolite N-Ac-5-ASA were in the range of 0.3 to 1.6 ug/ml. Peak plasma concentrations of 5-ASA are partially reached within the first hour of application.

Elimination

After a single rectal dose of 500 mg mesalazine, approximately 11% (within 72 hours) was recovered in the urine, and after several weeks of long-term treatment with 500 mg mesalazine three times daily as Melanez Suppositories approximately 13% of the 5-ASA dose administered was recovered in the urine. Approximately 10% of a single administered dose was eliminated via the bile.

Melanez Suppositories 1g specific:

Distribution:

Scintigraphic studies with a similar medicinal product, technetium-labelled Melanez Suppositories 500mg showed peak spread of the suppository that had melted due to body temperature after 2-3 hours. The spread was limited primarily to the rectum and rectosigmoid junction.It is assumed than Melanez Suppositories 1g act very similar and thus are particularly suitable for treating proctitis (ulcerative colitis of the rectum).

Absorption:

Mean peak plasma concentration of 5-ASA after a single rectal dose of 1g mesalazine (Melanez Suppositories 1g) were 192 ± 125 ng/ml (range 19-557 ng/ml), those of the main metabolite N-Ac-5-ASA were 402 ± 211 ng/ml (range 57-1070 ng/ml). Time to reach the peak plasma concentration of 5-ASA was 7.1± 4.9h (range 0.3-24 h).

Elimination:

After a single rectal dose of 1g mesalazine (Melanez Suppositories 1g) approx. 14% of the administered 5-ASA dose were recovered in the urine during 48 hours.

Indications

Melanez Suppositories 500mg: Acute episodes of ulcerative colitis, proctitis and inflammation of the anal canal.
Melanez Suppositories 1 g: Treatment of ulcerative proctitis.

Recommended Dosage

Posology

Adults and elderly

Melanez Suppositories 500mg:

One Mesalazine Suppositories 500mg three times daily (equivalent to 1500 mg mesalazine daily) inserted into the rectum, according to the individual clinical requirement. As soon as remission has occurred, Mesalazine 500 mg gastro-resistant tablets can be used.

Melanez Suppositories 1g:

One Melanez Suppositories 1 g, 1-2 times daily inserted into the rectum.

Children and adolescents

There is little experience and only limited documentation for an effect in children

Method of administration

When used three times daily, Mesalazine Suppositories 500mg should be inserted into the rectum in the morning, at midday and at bedtime.

Melanez Suppositories 1g should be administered preferably at bedtime.

Treatment with Melanez Suppositories must be administered regularly and consistently, because only in this way can healing be successfully achieved.

The duration of use is determined by the physician.

Route of Administration

For rectal administration only.

Contraindications

Melanez Suppositories are contraindicated in patients with:

- Known hypersensitivity to active substance, salicylates or to any of the excipients.
- Severe impairment of hepatic or renal function.

Warnings and Precautions

Blood tests (differential blood count; liver function parameters such as ALT or AST; serum creatinine) urinary status (dip-sticks) should be determined prior to and during treatment, at the discretion of the treating physician. As a guideline, follow-up tests are recommended 14 days after commencement of treatment, then a further two to three tests at intervals of 4 weeks.

If the findings are normal, follow-up tests should be carried out every 3 months. If additional symptoms occur, these tests should be performed immediately.

Caution is recommended in patients with impaired hepatic function.

Melanez Suppositories should not be used in patients with impaired renal function. Mesalazine-induced renal toxicity should be considered if renal function deteriorates during treatment.

Cases of nephrolithiasis have been reported with the use of mesalazine including stones with a 100% mesalazine content. It is recommended to ensure adequate fluid intake during treatment.

Patient with pulmonary disease, in particular asthma, should be very carefully monitored during a course of treatment with Melanez Suppositories.

Severe cutaneous adverse reactions

Severe cutaneous adverse reaction (SCARs), including Stevens-Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN), have been reported in association with mesalazine treatment.

Mesalazine should be discontinued, at the first appearance of signs and symptoms of severe skin reactions, such as skin rash, mucosal lesions, or any other sign of hypersensitivity.

Patients with a history of adverse drug reactions to preparations containing sulphasalazine should be kept under close medical surveillance on commencement of a course of treatment with Melanez Suppositories. Should Melanez Suppositories cause acute intolerance reactions such as abdominal cramps, acute abdominal pain, fever, severe headache and rash, therapy should be discontinued immediately.

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Photosensitivity

More severe reactions are reported in patients with pre-existings skin conditions such as atopic dermatitis and atopic eczema.

Interaction with Other Medicaments

Specific interaction studies have not been performed. In patients, who are concomitantly treated with azathioprine, 6-mercaptopurine or thioguanine, a possible increase in the myelosuppressive effects of azathioprine, 6-mercaptopurine or thioguanine should be taken into account. There is weak evidence that mesalazine might decrease the anticoagulant effect of warfarin.

Incompatibilities

Not available.

Pregnancy and Lactation

Pregnancy

There are no adequate data on the use of Melanez Suppositories in pregnant women. However, data on a limited number of exposed pregnancies indicate no adverse effect of mesalazine on the pregnancy or on the health of the foetus/newborn child. To date, no other relevant epidemiologic data are available. In one single case after long-term use of a high dose of mesalazine (2-4 g, orally) during pregnancy, renal failure in a neonate was reported.

Available published animal studies on oral mesalazine do not indicate direct or indirect harmful effects with respect to pregnancy, embryonic/ foetal development, parturition or postnatal development.

Melanez Suppositories should only be used during pregnancy if the potential benefit outweighs the possible risk.

Breast-feeding

N-acetyl-5-aminosalicyclic acid and to a lesser degree mesalazine are expected in breast milk. Only limited experience during lactation in women is available to date. Hypersensitivity reactions such as diarrhoea in the infant cannot be excluded. Therefore, Melanez Suppositories should only be used during breast-feeding, if the potential benefit outweighs the possible risk. If the infant develops diarrhoea, the breast-feeding should be discontinued.

Undesirable Effects

Organ Class System	Frequency According to MedDRA Convention		
	Rare)	Very rare	Not known
Blood and lymphatic system disorders		Altered blood counts (aplastic anaemia, agranulocytosis, pancytopenia, neutropenia, leukopenia, thrombocytopenia)	
Nervous system disorders	Headache, dizziness	Peripheral neuropathy	
Cardiac disorders	Myocarditis, pericarditis		
Respiratory, thoracic and mediastinal disorders		Allergic and fibrotic lung reactions (including dyspnoea, cough, bronchospasm, alveolitis, pulmonary eosinophilia, lung infiltration, pneumonitis)	
Gastrointestinal disorders	Abdominal pain, diarrhoea, flatulence, nausea, vomiting, constipation	Acute pancreatitis	
Renal and urinary disorders		Impairment of renal function including acute and chronic interstitial nephritis and renal insufficiency	Nephrolithiasis
Skin and subcutaneous tissue disorders	Photosensitivity	Alopecia	Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN)
Musculoskeletal and connective tissue disorders		Myalgia, arthralgia	
Immune system disorders		Hypersensitivity reactions such as allergic exanthema, drug fever, lupus erythematosus syndrome, pancolitis	
Hepatobiliary disorders		Changes in liver function parameters (increase in transaminases and parameters of cholestatic hepatitis)	
Reproductive system disorders		Oligospermia (Reversible)	

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Symptoms and Treatment of Overdosage

There are rare data on overdosage (e.g. intended suicide with high oral doses of mesalazine), which is do not indicate renal or hepatic toxicity. There are no specific antidote and treatment is symptomatic and supportive.

Effects on Ability to Drive and Use Machines

Melanez Suppositories have no or negligible influence on the ability to drive and use machines.

Instruction for Use

- When practical, clean the area around the rectum with mild soap and warm water and rinse thoroughly.
Gently dry by patting or blotting with toilet tissue or a soft cloth.
- Do not open suppository if it seems soft, hold the foil wrapper under cold water or place it in refrigerator
for few minutes to harden it before removing the wrapper.
- Position the patient to lie on one side with knees bent up to their abdomen or lie on back with feet and legs held up.
- Detach the suppository by holding strip upright and carefully peel the wrapper evenly down both sides.
(moisten the suppository if dry)
- Hold the suppository between index finger and thumb, locate the anus and gently insert suppository tip end first with the index finger. The suppository should be fully inserted in to rectum against the wall of rectum.
- Hold buttocks together lying down for about 5 minutes to avoid having the suppository comes out.
- Discard used materials and wash your hands thoroughly.

Storage Conditions

Store in a dry place, below 30°C. Protect from light

Shelf Life

24 months

Dosage Forms and Packaging Available

Melanez Suppositories 500 mg: 6 x 5 suppositories

Melanez Suppositories 1 g: 4 x 7 suppositories

Date of Revision: 25-Apr-2024



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