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Size	NA	
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PENTASA®
Mesalazine
Prolonged release tablets 500 mg

COMPOSITION
Each tablet contains 500 mg mesalazine.
Excipients: Magnesium stearate, talc, ethylcellulose, povidone, microcrystalline cellulose.

PHARMACEUTICAL DOSAGE FORM
Prolonged release tablets 500mg.
White grey to pale brown, speckled round tablets. Breakmark and embossing: 500 mg on one side, PENTASA on the other side.

INDICATIONS
Treatment of mild to moderate ulcerative colitis.

POSOLOGY AND METHOD OF ADMINISTRATION

Posology:
Ulcerative colitis
Treatment of active disease:
Adults: Individual dosage, up to 4 g given once daily or in divided doses.

Maintenance treatment:
Adults: Individual dosage. Recommended dosage, 2 g mesalazine once daily. Can also be taken in divided doses.

Method of administration:
PENTASA tablets must not be chewed. To facilitate swallowing, the tablets may be dispersed in 50 ml of cold water. Stir and drink immediately.

CONTRAINDICATIONS
Hypersensitivity to mesalazine, any of the excipients, or salicylates.
Severe liver or renal impairment.

SPECIAL WARNINGS AND PRECAUTIONS FOR USE
Most patients who are intolerant or hypersensitive to sulphasalazine are able to take PENTASA without risk of similar reactions. However, caution is recommended when treating patients allergic to sulphasalazine (risk of allergy to salicylates). Severe cutaneous adverse reactions (SCARs), including Drug reaction with eosinophilia and systemic symptoms (DRESS),Stevens-Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN), have been reported in association with mesalazine treatment. In case of acute intolerance reactions such as abdominal cramps, acute abdominal pain, fever and severe headache and/or the first appearance of signs and symptoms of severe skin reactions, such as skin rash, mucosal lesions, or any other signs of hypersensitivity, therapy should be discontinued immediately.

Caution is recommended in patients with impaired liver function. Liver function parameters like ALT or AST should be assessed prior to and during treatment, at the discretion of the treating physician.

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Renal impairment
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. Urinary status (dip sticks) should be determined prior to and during treatment at the discretion of the treating physician. Mesalazine induced nephrotoxicity should be suspected in patients developing renal dysfunction during treatment. **Mesalazine treatment should be discontinued immediately if renal function deteriorates.** The concurrent use of other known nephrotoxic agents should increase monitoring frequency of renal function.

Patients with pulmonary disease, in particular asthma, should be very carefully monitored during a course of treatment; please refer to section Undesirable effects.

Mesalazine-induced cardiac hypersensitivity reactions (myo- and pericarditis) have been reported rarely. Serious blood dyscrasias have been reported very rarely with mesalazine. Haematological investigations should be performed if the patient develops unexplained bleeding, bruising, purpura, anaemia, fever or sore throat. Treatment should be stopped if there is suspicion or evidence of blood dyscrasia. Also, blood test for differential blood count is recommended prior to and during treatment, at the discretion of the treating physician. As stated in the interaction section, concomitant treatment with mesalazine can increase the risk of blood dyscrasia in patients receiving azathioprine, or 6-mercaptopurine or thioguanine. Treatment should be discontinued on suspicion or evidence of these adverse reactions.

Patients with inflammatory bowel disease are at risk of developing nephrolithiasis. Cases of nephrolithiasis have been reported with the use of mesalazine including kidney stones composed entirely of mesalazine. It is recommended to ensure adequate fluid intake during treatment.

Use in the elderly: Age related factors (such as altered renal and hepatic function and polypharmacy) should be taken into consideration

Blood tests (differential blood count; liver function parameters such as ALT or AST; serum creatinine) and 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 three months. If additional symptoms occur, these tests should be performed immediately.

Mesalazine may produce red-brown urine discoloration after contact with sodium hypochlorite bleach (e.g., in toilets cleaned with sodium hypochlorite contained in certain bleaches)

INTERACTION WITH OTHER MEDICINAL PRODUCTS AND OTHER FORMS OF INTERACTION
Whilst there are no data on interactions between PENTASA and other drugs, in common with other salicylates, interactions may occur during concomitant administration of mesalazine and the following drugs:

- Coumarin type anticoagulants (e.g. warfarin sodium) – possible potentiation of the anticoagulant effect (increasing the risk of gastrointestinal haemorrhage)
- Glucocorticoids – possible increase in undesirable gastric effects
- Sulfonylureas – possible increase in the blood glucose lowering effects
- Methotrexate – possible increase in toxic potential of methotrexate
- Probenecid or sulfinpyrazone – possible attenuation of the uricosuric effects
- Spironolactone or frusemide – possible attenuation of the diuretic effects
- Rifampicin – possible attenuation of the tuberculostatic effects

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Combination therapy with PENTASA and azathioprine, or 6-mercaptopurine or thioguanine have in several studies shown a higher frequency of myelosuppressive effects, and an interaction seems to exist, however, the mechanism behind the interaction is not fully established. Regular monitoring of white blood cells is recommended and dosage regime of thiopurines should be adjusted accordingly.

FERTILITY, 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. The underlying condition itself (Inflammatory bowel disease/IBD) may increase risks for the pregnancy outcome.

Pregnancy
Pregnancy (Category C)

Oral administration of mesalazine during organogenesis in rats and rabbits at respective doses up to 1000 and 800 mg/kg/day was associated with concomitant embryofetal toxicity and maternotoxicity. At a dose of 1000 mg/kg/day in rats, fetuses showed enlarged brain ventricles. Non-embryofetal toxic and non-maternotoxic dosages were 500 and 400 mg/kg/day in rats and rabbits, respectively.

Mesalazine is known to cross the placental barrier and its concentration in umbilical cord plasma is lower than the concentration in maternal plasma. The metabolite acetylmesalazine is found at similar concentrations in umbilical cord and maternal plasma.

Animal studies on oral mesalazine do not indicate direct or indirect harmful effects with respect to pregnancy, embryo-foetal development, parturition or postnatal development. There are no adequate and well controlled studies of PENTASA use in pregnant women. Limited published human data on mesalazine show no increase in the overall rate of congenital malformations. Some data show an increased rate of preterm birth, stillbirth, and low birth weight; however, these adverse pregnancy outcomes are also associated with active inflammatory bowel disease.

Blood disorders (pancytopenia, leucopenia, thrombocytopenia, anaemia) have been reported in new-borns of mothers being treated with PENTASA.

Non-steroidal anti-inflammatory drugs inhibit prostaglandin synthesis and, when given during the latter part of pregnancy, may cause closure of the fetal ductus arteriosus, fetal renal impairment, inhibition of platelet aggregation, and delay labour and birth. Continuous treatment with non-steroidal anti-inflammatory drugs during the last trimester of pregnancy should only be given on sound indications. During the last few days before expected birth, agents with an inhibitory effect on prostaglandin synthesis should be avoided.

Data on 165 women exposed to mesalazine during pregnancy were prospectively collected and pregnancy outcome was compared with that of a control group. The investigators concluded that mesalazine does not represent a major teratogenic risk, as the reported rate of major malformations was within the expected baseline risk of the general population.

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.

PENTASA should be used with caution during pregnancy only if the potential benefits outweigh the possible hazards in the opinion of the physician. The underlying condition itself (inflammatory bowel disease/IBD) may increase risks for the pregnancy outcome.

Breastfeeding

Mesalazine is excreted in breast milk. The mesalazine concentration in breast milk is lower than in maternal blood, whereas the metabolite - acetyl-mesalazine - appears in similar or increased concentrations. There is limited experience of the use of oral mesalazine in lactating women. No controlled studies with PENTASA during breastfeeding have been carried out. Hypersensitivity reactions like diarrhoea in the infant cannot be excluded. Therefore, PENTASA should only be used during breast-feeding, if the potential benefit outweighs the possible risk. If the infant develops diarrhoea, breast-feeding should be discontinued.

Fertility
Animal data on mesalazine show no effect on male and female fertility.

EFFECTS ON ABILITY TO DRIVE AND USE MACHINES
Treatment with PENTASA is unlikely to affect the ability to drive and/or use machines.

UNDESIRABLE EFFECTS
Summary of the safety profile

The most frequent adverse reactions seen in clinical trials are diarrhoea, nausea, abdominal pain, headache, vomiting, and rash.
Hypersensitivity reactions and drug fever may occasionally occur including severe cutaneous adverse reactions, including Drug reaction with eosinophilia and systemic symptoms (DRESS) Stevens-Johnson Syndrome (SJS) and Toxic epidermal necrolysis (TEN), have been reported in association with mesalazine treatment (see SECTION SPECIAL WARNINGS AND PRECAUTIONS FOR USE). Mesalazine may be associated with an exacerbation of the symptoms of colitis in those patients who have previously had such problems with sulfasalazine.

Frequency of adverse effects, based on clinical trials and reports from postmarketing surveillance

MedDRA Organ Class	Common (≥1/100 to <1/10)	Rare (≥1/10,000 to <1/1,000)	Very rare (<1/10,000)	Not known (cannot be estimated from the available data).
Blood and the lymphatic system disorders			Altered blood counts (anaemia, aplastic anaemia, agranulocytosis, neutropenia, leukopenia (including granulocytopenia), pancytopenia, thrombocytopenia and eosinophilia (as part of an allergic reaction)	

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Immune system disorders			Hypersensitivity reaction including anaphylactic reaction	
Nervous system disorders	Headache	Dizziness	Peripheral neuropathy	
Cardiac disorders		Myo*- and pericarditis*		
Respiratory, thoracic and mediastenal disorders			Allergic and fibrotic lung reactions (including dyspnoea, coughing, bronchospasm, allergic alveolitis), pulmonary eosinophilia, interstitial lung disease, pulmonary infiltration, pneumonitis	
Gastrointestinal disorders	Diarrhoea, abdominal pain, nausea, vomiting, Flatulence	Increased amylase, acute pancreatitis*,	Pancolitis	
Hepato-biliary disorders			Increase in transaminases, increase in cholestasis parameters (e.g. alkaline phosphatase, gamma-glutamyltransferase and bilirubin), hepatotoxicity (incl. hepatitis*, cholestatic hepatitis, cirrhosis, hepatic failure)	
Skin and subcutaneous tissue disorders	Rash (incl. urticaria, erythematous rash)	Photosensitivity**	Alopecia Reversible, dermatitis allergic, erythema multiforme	Stevens-Johnson Syndrome (SJS)/Toxic epidermal necrolysis (TEN), Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS)
Musculoskeletal, connective tissue and bone disorders			Myalgia, arthralgia, lupus erythematosus-like syndrome (systemic lupus erythematosus)	

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Renal and urinary disorders			Renal function impairment (incl. acute and chronic interstitial nephritis*, nephrotic syndrome, renal insufficiency), Urine discolouration***	Nephrolithiasis ***
Reproductive system disorders			Oligospermia (reversible)	
General disorders and administration site conditions			Drug fever	

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

(**) Photosensitivity: More severe reactions are reported in patients with pre-existing skin conditions such as atopic dermatitis and atopic eczema.

(***) See section Special warnings and precautions for further information.

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

Adverse Event Reporting
If you notice any of the adverse events reactions mentioned above, or any adverse reactions not listed in this leaflet, please contact your doctor or nurse. You can also report these side effects to Ferring or the national reporting system provided below. Reporting side effects helps to gather more information about the safety of this medication.

PT Ferring Pharmaceuticals Industry
Safety Mailbox Indonesia
No Telp: (021) 50868801
Email: SafetyMaliboxIndonesia@ferring.com

Pusat MESO/Farmakovigilans Nasional
Direktorat Pengawasan Keamanan, Mutu dan Ekspor Impor Obat, Narkotika, Psikotropika, Prekursor dan Zat Adiktif
Badan POM RI
Jl. Percetakan Negara 23 Jakarta Pusat, 10560
No Telp: 021 – 4244691 Ext.1079
Email: pv-center@pom.go.id
Web : http://e-meso.pom.go.id/

OVERDOSAGE
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:
There is limited clinical experience with overdose of PENTASA. But since PENTASA is an amino salicylate, symptoms of salicylate toxicity may occur. Symptoms of mild salicylate intoxication include nausea, vomiting, tinnitus or dizziness. Symptoms of more severe salicylate intoxication include hyperthermia, dehydration, disturbance of electrolyte balance and blood pH, seizures, dysrhythmias, coagulopathy, renal failure and coma.

There have been reports of patients taking daily doses of 8 grams for a month without any adverse events.

Management of overdose in humans: There is no specific antidote. As PENTASA is an aminosalicylate, conventional therapy for salicylate toxicity may be beneficial. General supportive and symptomatic measures are recommended. Steps to prevent further gastrointestinal tract absorption may be appropriate. Fluid and electrolyte imbalance should be corrected by the administration of appropriate intravenous therapy. Renal function should be closely monitored.

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PHARMACODYNAMICS

Pharmacotherapeutic group: Intestinal anti-inflammatory agents (A07 EC02).

Mechanism of action and pharmacodynamic effects: It has been established that mesalazine is the active component of sulfasalazine, which is used for the treatment of ulcerative colitis.

Based on clinical results, the therapeutic value of mesalazine after oral as well as rectal administration appears to be due to local effect on the inflamed intestinal tissue, rather than to systemic effect. There is information suggesting that severity of colonic inflammation in ulcerative colitis patients treated with mesalazine is inversely correlated with mucosal concentrations of mesalazine.

Increased leucocyte migration, abnormal cytokine production, increased production of arachidonic acid metabolites, particularly leukotriene B4, and increased free radical formation in the inflamed intestinal tissue are all present in patients with IBD. The mechanism of action of mesalazine is not fully understood although mechanisms such as activation of the γ-form of peroxisome proliferator-activated receptors (PPAR-γ) and inhibition of nuclear factor-kappa B (NF-κB) in the intestinal mucosa have been implicated. Mesalazine has in-vitro and in-vivo pharmacological effects that inhibit leucocyte chemotaxis, decrease cytokine and leucotriene production, and scavenge for free radicals. It is currently unknown which, if any, of these mechanisms play a predominant role in the clinical efficacy of mesalazine.

The risk of colorectal cancer (CRC) is slightly increased in ulcerative colitis.
Observed effects of mesalazine in experimental models and patient biopsies support the role of mesalazine in prevention of colitis-associated CRC, with down regulation of both inflammation dependent and non-inflammation dependent signalling pathways involved in the development of colitis-associated CRC.

However, data from metaanalyses, including both referral and non-referral populations, provide inconsistent clinical information regarding the benefit of mesalazine in the carcinogenesis risk associated with ulcerative colitis.

PHARMACOKINETICS

General characteristics of the active substance

Disposition and local availability:
The therapeutic activity of mesalazine most likely depends on a local contact of the drug with the diseased area of the intestinal mucosa.

PENTASA prolonged release tablets consist of ethylcellulose-coated microgranules of mesalazine. Following administration and tablet disintegration, the microgranules act as discrete slow-release formulations which allow a continuous release of drug from duodenum to rectum at all enteral pH conditions. The microgranules enter the duodenum within an hour of administration, independent of food co-administration. In healthy volunteers the average small intestinal transit time is approximately 3-4 hours

Absorption:
Bioavailability of Pentasa after oral administration can be estimated to approx. 30% based on urine recovery data in healthy volunteers. Maximum plasma concentrations are seen 1-6 hours post-dose. A once-daily dosing regimen of mesalazine (1 × 4 g/d) and a twice-daily dosage (2 × 2 g/d) results in a comparable systemic exposure (AUC) over 24 hours and indicate a continuous release of mesalazine from the formulation over the treatment period. Steady-state is reached after a treatment period of 5 days following oral administration.

Single dose	Steady state

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	Cmax (ng/mL)	AUC 0-24 (h·ng/mL)	Cmax (ng/mL)	AUC 0-24 (h·ng/mL)
Mesalazine				
2 g BID	5103.51	36,456	6803.70	57,519
4 g OD	8561.36	35,657	9742.51	50,742

Molecular weight of mesalazine: 153.13 g/moL; Ac-mesalazine: 195.17 g/moL.

Mean steady-state plasma concentrations of mesalazine are approximately 0.3 µg/mL, 1.2 µg/mL and 1.9 µg/mL after 1.5 g, 4 g and 6 g daily dosages, respectively. For acetyl-mesalazine the corresponding concentrations are approximately 1.1 µg/mL, 2.5 µg/mL and 3.1 µg/mL.

The transit and release of mesalazine after oral administration are independent of food co-administration, whereas the systemic exposure may be increased.

Distribution:
Protein binding of mesalazine is approximately 50% and of acetyl-mesalazine about 80%.

Metabolism:
Mesalazine is metabolised both pre-systemically by the intestinal mucosa and systemically in the liver to N-acetyl-mesalazine (acetyl-mesalazine) principally by NAT-1. Some acetylation also occurs through the action of colonic bacteria. The acetylation seems to be independent of the acetylator phenotype of the patient.

The metabolic ratio of acetyl-mesalazine to mesalazine in plasma after oral administration ranges from 3.5 to 1.3 after daily doses of 500 mgx3 and 2 gx3, respectively, implying a dose-dependent acetylation which may be subject to saturation.

Elimination:
After intravenous administration, the plasma half-life of mesalazine is approximately 40 minutes and for acetylmesalazine approximately 80 minutes. Due to the continuous release of mesalazine from PENTASA throughout the gastrointestinal tract, the elimination half-life cannot be determined after oral administration. However, steady-state is reached after a treatment period of 5 days following oral administration.

Both substances are excreted in urine and faeces. The urinary excretion consists mainly of acetyl mesalazine and the faecal excretion consists mainly of mesalazine.

Characteristics in patients
Pathophysiologic changes such as diarrhoea and increased bowel acidity observed during active inflammatory bowel disease has only a minor impact on the delivery of mesalazine to the intestinal mucosa after oral administration. A reduction in systemic absorption to 20-25% of the daily dose has been observed in patients with accelerated intestinal transit.. Likewise, a corresponding increase in faecal excretion has been seen.

In patients with impaired liver and kidney functions, the resultant decrease in the rate of elimination and increased systemic concentration of mesalazine may constitute an increased risk of nephrotoxic adverse reactions.

PRECLINICAL SAFETY DATA
Toxic renal effects have been demonstrated in all species tested. Rat and monkey dosages and plasma concentrations at the No Observed Adverse Effect Levels (NOAELs) exceed those used in humans by a factor of 2-7.2.

No significant toxicity associated with the gastrointestinal tract, liver or haematopoietic system in animals has been observed.

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In vitro test systems and in-vivo studies showed no evidence of mutagenic or clastogenic effects. Studies of the tumourigenic potential carried out in mice and rats showed no evidence of any substance-related increase in the incidence of tumours.

Animal studies on oral mesalazine do not indicate direct or indirect harmful effects with respect to fertility, pregnancy, embryo-foetal development, parturition or postnatal development.

Mesalazine is deemed not to pose a risk to the environment at the doses prescribed for use in patients.

INCOMPATIBILITIES
None known.

SHELF-LIFE
3 years.

SPECIAL PRECAUTION FOR STORAGE
Store below 30ºC. Store in the original package, as the product is sensitive to light. Do not freeze

SPECIAL PRECAUTIONS FOR DISPOSAL
No special requirements.
Any unused product or waste should be disposed of in accordance with local requirements.

NATURE AND CONTENTS OF CONTAINER
Double aluminium foil blisters.

Pack size:
Box of 10 blisters @ 10 prolonged release tablets (Reg. No.: DKI XXXXXXXXXXX)

MANUFACTURER
Ferring International Center SA
St. Prex, Switzerland

Released by:
Ferring International Center SA
St. Prex, Switzerland

IMPORTED BY
PT Ferring Pharmaceuticals Industry
Tangerang Selatan – Indonesia

HARUS DENGAN RESEP DOKTER

Date of revision: 17 November 2025

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Informasi untuk pasien
Tablet PENTASA lepas lambat 500 mg
Mesalazine

Bacalah seluruh isi leaflet ini dengan seksama sebelum Anda mulai menggunakan obat ini karena leaflet ini mengandung informasi penting untuk Anda. Obat ini hanya diresepkan untuk Anda. Jangan memberikan kepada orang lain. Hal ini dapat membahayakan orang lain, meskipun mereka memiliki gejala yang sama dengan Anda.
- Simpanlah leaflet ini, sebab Anda mungkin perlu membacanya lagi dikemudian hari.
- Apabila Anda memiliki pertanyaan lebih lanjut, tanyakan pada dokter Anda.
- Jika Anda mengalami efek samping, bicarakan dengan dokter Anda. Termasuk efek samping yang mungkin tidak tercantum dalam leaflet ini. Lihat bagian 4.

Apa isi leaflet ini?

1. Apa itu tablet PENTASA lepas lambat dan apa kegunaannya

Bahan aktif PENTASA adalah mesalazine, yang termasuk dalam kelompok obat-obatan yang dikenal dengan salisilat. Zat ini memiliki efek penyembuhan pada peradangan (pembengkakan, kemerahan dan nyeri) di usus yang disebabkan oleh kondisi seperti kolitis ulserativa.

PENTASA digunakan untuk pengobatan serangan kolitis ulserativa ringan sampai sedang. Obat ini juga digunakan untuk membantu menjaga agar terbebas dari serangan lebih lanjut. .

2. Apa yang perlu Anda ketahui sebelum menggunakan tablet PENTASA lepas lambat

Jangan gunakan tablet PENTASA lepas lambat:
- Jika Anda hipersensitif (alergi) terhadap mesalazine atau bahan lain dari obat ini (tercantum pada bagian 6)
- Jika Anda alergi terhadap salisilat lainnya
- Jika Anda memiliki masalah liver dan/atau ginjal yang parah. Hentikan penggunaan mesalazine segera jika fungsi ginjal Anda menurun atau memburuk.

Peringatan dan tindakan pencegahan
Harap beritahukan ke dokter jika Anda mengalami hal-hal berikut:
- Jika Anda alergi terhadap sulphasalazine (salisilat)
- Jika saat ini Anda memiliki atau pernah mengalami penyakit liver atau ginjal sebelumnya
- Jika Anda sedang menggunakan obat yang dapat mempengaruhi fungsi ginjal
- Jika Anda memiliki masalah paru-paru, khususnya asma
- Jika Anda tiba-tiba mengalami kram perut, nyeri perut, demam, sakit kepala berat dan ruam.
- Jika Anda mengalami perdarahan, memar, ruam kulit, demam-atau sakit tenggorokan ketika mengkonsumsi obat ini, hentikan penggunaan obat dan segera konsultasikan dengan dokter.
- Jika Anda mengalami nyeri dada, peningkatan detak jantung dan merasa kelelahan yang berlebih ketika mengkonsumsi obat ini, hentikan penggunaan obat dan segera konsultasikan dengan dokter.

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- Batu ginjal dapat terbentuk karena penggunaan mesalazine. Gejala dapat berupa nyeri pada perut dan darah pada urin. Minum air dalam jumlah cukup selama menggunakan mesalazine.
- Jika Anda mengalami ruam kulit parah atau kulit mengelupas, melepuh dan/atau sariawan setelah menggunakan mesalazine

Dalam keadaan seperti itu Anda harus segera berhenti meminum PENTASA.

Ketika Anda dalam perawatan dengan obat ini, dokter Anda biasanya akan menjadwalkan tes darah dan urin untuk memeriksa fungsi ginjal Anda terutama pada awal-awal pengobatan.

Mesalazine dapat menyebabkan perubahan warna urin menjadi merah kecoklatan setelah kontak dengan pemutih natrium hipoklorit (misalnya, di toilet yang dibersihkan dengan natrium hipoklorit yang terkandung dalam pemutih tertentu)

Obat lain dan tablet PENTASA lepas lambat
Beritahu dokter atau apoteker Anda jika Anda sedang meminum/ menggunakan, baru-baru ini telah meminum/ menggunakan atau mungkin akan meminum/ menggunakan obat lainnya. Hal ini sangat penting jika Anda menggunakan salah satu dari berikut ini:
- Azatioprin (digunakan setelah transplantasi atau untuk mengobati penyakit auto-imun)
- 6-mercaptopurine atau thioguanine (kemoterapi, digunakan untuk mengobati leukemia)
- Obat-obat tertentu yang menghambat penggumpalan darah (obat untuk trombosis atau mengencerkan darah Anda).

Kehamilan, menyusui dan kesuburan
Jika Anda sedang hamil atau menyusui, Anda pikir mungkin hamil atau berencana untuk hamil, mintalah nasihat dokter atau apoteker sebelum minum obat ini.
Ada keterbatasan pengalaman dengan penggunaan mesalazine selama kehamilan dan menyusui. Bayi baru lahir dapat mengalami reaksi alergi setelah menyusui, contoh: diare. Jika bayi baru lahir mengalami diare, maka menyusui harus dihentikan.

Mengemudi dan menggunakan mesin
Obat ini tidak diketahui apakah dapat mempengaruhi kemampuan mengemudi dan/atau menggunakan mesin.

3. Cara menggunakan PENTASA tablet lepas lambat
Penggunaan pada orang dewasa:
Untuk mengobati serangan:
- Kolitis ulserativa, dokter Anda biasanya akan meresepkan dosis hingga 4 g mesalazine sehari untuk diminum sekali sehari atau dalam dosis terbagi.

Obat ini mungkin diminum sampai delapan tablet 500 mg.

Untuk membantu menjaga terbebas dari serangan lebih lanjut:
- Kolitis ulserativa, dokter Anda biasanya akan meresepkan 2 g mesalazine sehari untuk diminum sekali sehari atau dalam dosis terbagi.

Obat ini dapat diminum sebagai empat tablet 500 mg.

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Cara pemberian

Tablet PENTASA harus digunakan secara oral (diminum)

Untuk membantu Anda menelan tabletnya, Anda bisa melarutkan tabletnya ke dalam 50 ml air dingin. Aduk dan minum segera.

Tablet PENTASA tidak boleh dikunyah.

Jika Anda meminum PENTASA lebih banyak daripada yang seharusnya

Jika terjadi overdosis, segera hubungi dokter Anda.

Jika Anda lupa meminum/ menggunakan PENTASA

Jika Anda lupa minum satu dosis, maka minumlah segera ketika Anda ingat, lalu minumlah dosis berikutnya pada waktu yang biasa. Jangan meminum dosis ganda untuk menggantikan dosis yang terlupakan.

Jika Anda mempunyai pertanyaan lebih lanjut tentang penggunaan obat ini, tanyakan kepada dokter, apoteker atau perawat Anda.

4. Efek samping yang mungkin terjadi

Seperti semua obat lainnya, obat ini bisa menimbulkan efek samping, meski tidak semua orang mendapatkannya.

Efek samping umum berikut ini dapat mengenai hingga 1 dari 10 orang:

- sakit kepala
- diare
- nyeri perut
- mual
- muntah
- perut kembung (buang angin)
- ruam

Efek samping yang jarang berikut ini dapat mempengaruhi hingga 1 dari 1.000 orang:

- radang pada beberapa area di jantung (miokarditis dan perikarditis) yang dapat menyebabkan sesak napas dan nyeri dada atau palpitasi (detak jantung yang kencang atau tidak teratur)
- radang pankreas (gejala termasuk sakit punggung dan/atau sakit perut).
- peningkatan amilase (enzim yang membantu mencerna karbohidrat)
- pusing
- kulit atau mata sangat sensitif terhadap cahaya (gejala seperti ruam, kulit terbakar, nyeri atau lepuh)

Efek samping berikut yang sangat jarang terjadi dapat mengenai hingga 1 dari 10.000 orang:

- anemia dan kelainan darah lainnya (penurunan atau kenaikan jumlah sel darah tertentu)
- reaksi alergi termasuk reaksi anafilaksis (reaksi alergi berat, gejala seperti gatal-gatal di seluruh tubuh, kesulitan bernafas, tenggorokan terasa tercekik atau susah menelan)
- neuropati perifer (kondisi yang mempengaruhi saraf tangan dan kaki). Gejala termasuk kesemutan dan mati rasa)
- reaksi paru-paru alergik dan fibrotik, radang pada lapisan paru-paru atau jaringan paru-paru (gejala termasuk sesak nafas, batuk, bronkospasme, ketidaknyamanan dada atau nyeri dada ketika bernapas, kesulitan bernapas, berdarah dan/atau dahak berlebihan)
- peradangan usus besar kronis, gejala seperti nyeri perut, diare, sering ingin buang air besar

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hingga pendarahan)
- kelainan liver (gejala termasuk penyakit kuning (menguningnya kulit dan/atau mata) dan/atau kotoran berwarna terang atau pucat putih keabu-abuan), nyeri otot atau persendian
- reaksi alergi pada kulit (gejala seperti kulit kemerahan, lecet melepuh, kulit bersisik, terasa sakit saat disentuh), kerontokan pada rambut yang bersifat reversible karena rembut dapat tumbuh kembali tanpa perawatan tambahan
- kelainan otot dan jaringannya (gejala termasuk nyeri otot, nyeri sendi, sindrom mirip lupus eritematosus (SLE))
- kelainan ginjal (gejala termasuk darah dalam urin, dan/atau edema (pembengkakan akibat penumpukan cairan, perubahan warna urin)
- kelainan sistem reproduksi (Oligospermia)
- demam

BERHENTI menggunakan Pentasa dan segera dapatkan bantuan medis jika Anda melihat salah satu dari gejala berikut:
- Bercak kemerahan ditubuh, seperti spesifik atau bercak melingkar pada batang tubuh, seringkali disertai dengan lepuh di bagian tengah, kulit mengelupas, sariawan pada mulut, tenggorokan, hidung, alat kelamin dan mata. Ruam kulit yang serius ini dapat didahului oleh demam dan gejala seperti flu
- Gatal, ruam kulit, pembengkakan wajah, bibir atau tenggorokan, kesulitan bernapas atau mengi (tanda-tanda reaksi alergi).
- Pendarahan yang tidak dapat dijelaskan, memar, ruam kulit, demam atau sakit tenggorokan (tanda-tanda kelainan darah)
- Perubahan warna atau jumlah urin yang dihasilkan (tanda-tanda masalah ginjal). Jika Anda mengalami salah satu dari efek samping di atas, Anda harus menghubungi dokter Anda atau segera pergi ke unit gawat darurat rumah sakit terdekat

Pelaporan Kejadian yang Tidak Diinginkan (Adverse Event Reporting)
Jika Anda mengalami salah satu reaksi yang tidak diinginkan seperti yang disebutkan di atas, atau reaksi yang tidak tercantum dalam leaflet ini, harap segera hubungi dokter atau perawat Anda. Anda juga dapat melaporkan efek samping tersebut kepada Ferring atau sistem pelaporan nasional yang tercantum di bawah ini. Pelaporan efek samping membantu mengumpulkan lebih banyak informasi mengenai keamanan obat ini.

PT Ferring Pharmaceuticals Industry
Safety Mailbox Indonesia
No. Telp: (021) 50868801
Email: SafetyMaliboxIndonesia@ferring.com

5. Bagaimana cara penyimpanan tablet PENTASA lepas lambat

Jauhkan obat ini dari pandangan dan jangkauan anak-anak.
Jangan gunakan obat ini setelah tanggal kadaluwarsa yang tercantum pada karton dan foil.
Tanggal kadaluwarsa mengacu pada hari terakhir bulan itu.

Simpan di bawah suhu 30° C.
Simpan dalam kemasan aslinya agar terlindung dari cahaya.
Jangan dibekukan.

Jangan membuang obat apapun melalui air limbah atau limbah rumah tangga. Tanyakan apoteker Anda bagaimana cara membuang obat yang tidak anda gunakan lagi. Langkah-langkah ini akan membantu melindungi lingkungan.

5. Isi kemasan dan informasi lainnya

Apa isi tablet PENTASA lepas lambat
- Zat aktif : Mesalazine

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- Eksipien lain : Magnesium stearat, talc, etilselulosa, povidon, selulosa mikrokristalin

Seperti apa tablet PENTASA lepas lambat dan bagaimana isi kemasannya
Obat ini mengandung tablet lepas lambat. Tablet berwarna putih keabu-abuan sampai coklat pucat, tablet bundar berbintik-bintik. Ada tanda skor dan diembos: 500 mg di satu sisi, dan PENTASA di sisi lain

Tablet lepas lambat dikemas dalam blister dobel aluminium foil, masing-masing berisi 10 tablet.

Pack size:
Box of 10 blisters @ 10 prolonged release tablets (Reg. No.: DKI XXXXXXXXXXX)

Pemegang Hak Pemasaran dan Produsen

Diproduksi oleh:

Ferring International Center

SA St Prex – Switzerland

Dirilis oleh:

Ferring International Center

SA St Prex – Switzerland

Diimpor oleh:
PT Ferring Pharmaceuticals Industry
Tangerang Selatan – Indonesia

HARUS DENGAN RESEP DOKTER

Leaflet ini terakhir direvisi pada bulan November 2025