Proposed packaging material		
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PENTASA®
Mesalazine
Enema 1g

COMPOSITION
Each enema contains 1 g mesalazine.
Excipients: Disodium edetate, sodium metabisulphite, sodium acetate, purified water, hydrochloric acid for pH adjustment.

PHARMACEUTICAL DOSAGE FORM
Enema (rectal suspension)
White to slightly yellow suspension with a pH value between 4.4 and 5.0.

INDICATIONS
Treatment of mild to moderate ulcerative proctosigmoiditis

POSOLOGY AND METHOD OF ADMINISTRATION
Posology:
1 enema at bedtime

Paediatric population:
Not recommended

Method of administration:
A visit to the toilet is recommended before administration of enemas.

Instructions for use:
Shake the enema container well before use. The enema is protected by an aluminium foil bag and should be used immediately after opening of the bag.
The enema may colour the linen and toilet.

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, including 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.

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. 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. 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 nephroithiasis with mesalazine content have been reported during treatment with mesalazine. Adequate fluid intake must be ensured during treatment.

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.

INTERACTION WITH OTHER MEDICINAL PRODUCTS AND OTHER FORMS OF INTERACTION

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.

There is weak evidence that mesalazine might decrease the anticoagulant effect of warfarin

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

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.
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.

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. 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
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, and severe cutaneous adverse reactions, including SJS and TEN, have been reported in association with mesalazine treatment (see section Special warnings and precautions for use).
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 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, Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS),	
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, gammaglutamyltransferase 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)
Musculoskeletal, connective tissue and bone disorders			Myalgia, arthralgia, lupus erythematosus like syndrome (systemic lupus erythematosus)	
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	Only with rectal form: Anal discomfort and irritation at the application site, pruritus, tenesmus		Drug fever	

(*) 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 use for further information.

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

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare professionals are asked to report any suspected adverse reactions to : pv-center@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 which does not indicate renal or hepatic toxicity. Since PENTASA is an amino salicylate, symptoms of salicylate toxicity, such as acid-base balance disorder, hyperventilation, pulmonary edema, vomiting, dehydration and hypoglycaemia, may occur. Symptoms of salicylate over dosage are well described in the literature.

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

There is no specific antidote and the management of overdose is supportive and symptomatic. The treatment at the hospital includes close monitoring of renal function.

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 and Crohn's disease.

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 mezalamine.

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 has 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.

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 suppositories and enemas are designed to provide the distal part of the intestinal tract with high concentrations of mesalazine and a low systemic absorption. Suppositories cover the rectum, whereas enemas have been shown to reach and cover the descending colon.

Absorption:
The absorption following rectal administration is low, and depends on the dose, the formulation and the extent of spread. Based on urine recoveries in healthy volunteers under steady-state conditions given a daily dose of 2 g (1 g x 2), approximately 10% of the dose is absorbed after administration of suppositories whereas about 15-20% is absorbed after administration of enemas.

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.

Excretion:
After intravenous administration, the plasma half-life of mesalazine is approximately 40 minutes and for acetyl-mesalazine approximately 80 minutes. Due to an absorption-limited elimination following rectal administration, mesalazine has an apparent half-life of up to 7 hours, and the metabolite, acetyl-mesalazine, shows an apparent half-life of up to 11 hours. Both substances are excreted in the urine and faeces. The urinary excretion consists mainly of acetylmesalazine and the faeces consist mainly of mesalazine.

Characteristics in patients

The systemic exposure following administration of PENTASA enemas has been shown to be significantly decreased in patients with active ulcerative colitis as compared to those in remission.

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.

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

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
2 years.

STORAGE
Store below 30°C. Do not refrigerate or freeze.
Store in the original package, as the product is sensitive to light

PACKING SIZE
Box of 7 bottles in aluminium foil bags @ 100 ml (Reg. No.: DKI 2050600258A1)

MANUFACTURER
Ferring-Léčiva, a.s.
Czech Republic

IMPORTED BY
PT. Abbott Indonesia
Jakarta – Indonesia

HARUS DENGAN RESEP DOKTER

Date of revision: 07-Des-2021

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Informasi untuk pasien

Pentasa 1 g Enema

Mesalazine

Bacalah seluruh isi leaflet ini dengan seksama sebelum Anda mulai menggunakan obat ini karena leaflet ini mengandung informasi penting untuk 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 PENTASA ENEMA 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 proktosigmoiditis ulserativa

PENTASA digunakan untuk pengobatan proktosigmoiditis ulserativa (peradangan pada bagian terakhir kolon dan rektum (lorong bagian belakang))

2. Apa yang perlu Anda ketahui sebelum menggunakan PENTASA ENEMA

Jangan gunakan PENTASA ENEMA:

- Jika Anda hipersensitif (alergi) terhadap mesalazine atau bahan lain dari obat ini (tercantum pada bagian 6)
- Jika Anda alergi terhadap salisilat lainnya. Beberapa gejala reaksi alergi seperti: nafas pendek, bersin, sulit bernafas, pembengkakan pada wajah, bibir, lidah atau bagain tubuh lainnya, ruam, gatal-gatal pada kulit.
- Jika Anda memiliki masalah liver dan/atau ginjal yang parah

Peringatan dan tindakan pencegahan

- Harap konsultasikan ke dokter Adda sebelum menggunakan enema:
  - 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

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- Jika Anda tiba-tiba mengalami kram perut, nyeri perut, demam, sakit kepala berat dan ruam, hentikan penggunaan obat dan segera konsultasikan ke dokter. Pastikan diri Anda tidak mengalama dehidrasi yang terjadi karena muntah dan/atau diare yang berkepanjangan, demam tinggi dan banyak berkeringat. Jika hal ini terjadi, segera konsultasikan ke dokter atau apoteker Anda.
- 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

Obat lain dan PENTASA ENEMA
Beritahu dokter atau apoteker Anda jika Anda sedang meminum/ menggunakan, baru-baru ini telah meminum/ menggunakan atau mungkin akan meminum/ menggunakan obat-obatan 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, seperti 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 ENEMA

Dosis yang dianjurkan adalah:
Orang dewasa: 1 enema saat jam tidur

Anak-anak dan remaja: tidak dianjurkan

Cara pemberian:
Kunjungan ke toilet dianjurkan sebelum pemberian enema
Produk atau limbah yang tidak terpakai harus dibuang sesuai dengan persyaratan lokal.

Kocok dengan baik wadah enema sebelum digunakan. Enema dilindungi dengan kantung aluminium foil dan harus segera digunakan setelah dibuka kantungnya.
Enema bisa membuat warna pada linen dan toilet.

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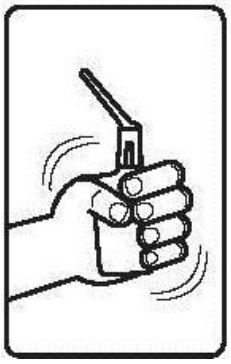
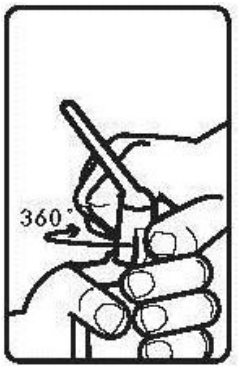
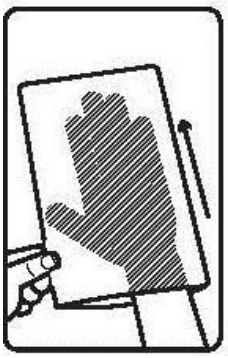


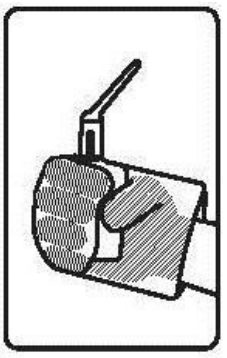
1. Segera sebelum penggunaan ambil botol enema dari kemasan aluminium foil dan kocok dengan baik.



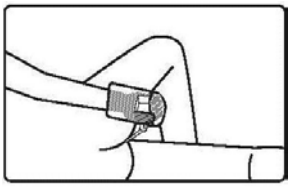
2. Untuk membuka segelnya, putar nosel-nya searah jarum jam satu putaran penuh (nosel-nya kemudian harus berada pada arah yang sama seperti sebelum diputar).



3. Masukkan tangan Anda di salah satu kantong plastik pembuangan yang disediakan dalam kemasannya.

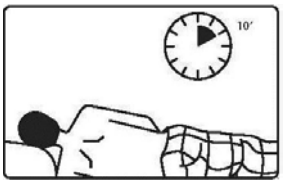


4. Pegang wadahnya seperti yang ditunjukkan pada gambar.

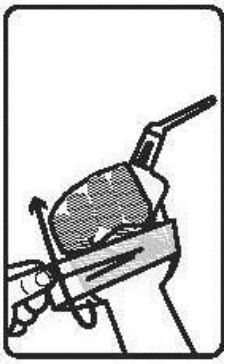


5. Untuk pemberian enema tersebut, berbaringlah di sisi kiri dengan kaki kiri lurus dan kaki kanan ditekuk ke depan untuk keseimbangan. Masukkan ujung aplikatornya dengan hati-hati ke dalam rektum. Pertahankan tekanan tangan yang cukup stabil sewaktu menyemprotkan isi botolnya. Isi botol harus dimasukkan maksimal 30-40 detik

6. Setelah botol kosong, tarik ujungnya dengan posisi botol masih tetap ditekan.



7. Enema harus dipertahankan di usus. Tetaplah rileks pada posisi pemberian selama 5-10 menit atau sampai dorongan untuk meloloskan enema sudah tidak ada.



8. Gulung kantong plastik pembuangannya sampai melewati botol kosongnya. Buang semuanya dan cuci tangan Anda.

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4. Efek samping yang mungkin

Seperti semua obat-obatan, 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
- Hanya untuk formulasi rektal: Ketidaknyamanan dan iritasi pada anus di tempat pemasukkan, gatal dan rasa buang air besar yang tidak lampias (tenesmus).

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
- sensitif terhadap cahaya

Efek samping berikut yang sangat jarang terjadi dapat mengenai hingga 1 dari 10.000 orang:
- anemia dan kelainan darah lainnya (penurunan jumlah sel darah tertentu, yang dapat menyebabkan pendarahan yang tidak dapat dijelaskan, memar, demam atau sakit tenggorokan)
- reaksi alergi (radang) yang dapat mempengaruhi bagian tubuh yang berbeda-beda seperti persendian, kulit, ginjal, jantung dll.
- 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 parut paru (gejala termasuk batuk, bronkospasme, ketidaknyamanan dada atau nyeri dada ketika bernapas, kesulitan bernapas, berdarah dan/atau dahak berlebihan)
- kelainan liver (gejala termasuk penyakit kuning (menguningnya kulit dan/atau mata) dan/atau kotoran berwarna pucat)
- nyeri otot atau persendian
- kelainan ginjal (gejala termasuk darah dalam urin, dan/atau edema (pembengkakan akibat penumpukan cairan))
- perubahan warna urin

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Changes	Editorial update at PUSAT Meso section	
Reference	☐CCDS version: ☒ Core PIL version: R-Core PIL-39734;Ver. 1.0, 02 Jan 2017	☐SPC country/version/date: ☐LAC no.:
Name & Date	INS, 05-Mar-2021	

Pelaporan efek samping
Jika Anda mendapatkan efek samping diatas, hubungi dokter, bidan atau perawat Anda. Hal yang sama berlaku untuk efek samping yang tidak tercantum dalam leaflet ini. Anda juga dapat melaporkan efek samping tersebut ke sistem pelaporan nasional dibawah ini. Dengan melaporkan efek samping, Anda dapat membantu memberikan informasi lebih lanjut tentang keamanan obat ini.

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 - 4244 755 ext.111
Fax : 021 - 4288 3485
Email : pv-center@pom.go.id

5. Bagaimana cara penyimpanan PENTASA ENEMA

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

Simpan pada suhu di bawah 30°C.
Jangan didinginkan atau dibekukan.
Simpan dalam kemasan asli agar terlindung dari cahaya.

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.

6. Isi kemasan dan informasi

lainnya Apa isi PENTASA ENEMA
- Zat aktif: Mesalazine
- Eksipien lain: Disodium edetate, sodium metabisulphite, sodium asetat, air murni, asam klorida untuk penyesuaian pH.

Seperti apa PENTASA ENEMA dan bagaimana isi kemasannya
Suspensi putih sampai agak kekuningan.
Obat disediakan dalam botol polyethylene dengan ujung berkatup untuk aplikasi ke dalam dubur. Botol disediakan dalam kantong aluminium foil yang diisi nitrogen.

Pemegang Hak Pemasaran dan Produsen
Diproduksi oleh:
Ferring-Léčiva, a.s. Czech Republic

Diimpor oleh:
PT. Abbott Indonesia
Jakarta – Indonesia

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HARUS DENGAN RESEP DOKTER

Leaflet ini terakhir direvisi pada 05-Mar-2021