Proposed packaging material		
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Size	NA	
Submission	☐NDA ☐Renewal ☒Variation change detail no.: #220753	
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Reference	☒CCDS version: CCDS Ver.19 ☐Core PIL version:	☐SPC country/version/date: ☐LAC no.:
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PENTASA®

Mesalazine

Suppositories 1g

COMPOSITION

Each suppository contains 1 g mesalazine.
Excipients: magnesium stearate, talc, povidone, macrogol 6000.

PHARMACEUTICAL DOSAGE FORM

Suppositories 1 g
White to tan, spotted, oblong suppositories

INDICATIONS

Treatment of ulcerative proctitis.

DOSAGE AND ADMINISTRATION

Adults : 1 suppository 1-2 times daily.

INSTRUCTION FOR USE

1. A visit to the toilet is recommended before inserting a suppository.
2. Open the foil bag at the tear mark.
3. The suppository is inserted in the rectum until resistance is felt and disappeared 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.

CONTRAINDICATIONS

Children under the age of 15 years.
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.

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. Blood test for differential blood count is recommended prior to and during treatment, at the discretion of the treating physician.As stated in section Interaction with Other Medicinal Product and Other Forms of Interaction, 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.

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

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.

The concomitant use of mesalazine with other known nephrotoxic agents, such as NSAIDs and azathioprine, may increase the risk of renal reactions.

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 adverse pregnancy outcome.

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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 breast-feeding 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

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, and 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).

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

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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)	
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	

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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)**
Hepato-biliary disorders			Increase in transaminases, increase in cholestasis parameters (e.g. alkaline phosphatase, gammaglutamyltrans fe rase 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)	
Renal and urinary disorders			Renal function impairment (incl. acute and chronic interstitial nephritis*, nephrotic syndrome, renal insufficiency), Urine discolouration***	Nephrolithiasis ***
Reproducti ve system disorders			Oligospermia (reversible)	
General disorders and administration site conditions	Only with rectal form: Anal discomfort and irritation at the application site, pruritus(anal), rectal 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.

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 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 proctitis.
Based on clinical results, the therapeutic value of mesalazine after 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-

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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.

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 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.

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 2g (1g x 2), approximately 10% of the dose is absorbed after administration of suppositories.

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.

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.

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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.

STORAGE
Store below 30°C. Store in the original package, as the product is sensitive to light.

PACKING SIZES
Double aluminium foil blisters. Box of 4 blisters x 7 suppositories.

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

MANUFACTURER
Ferring International Center SA Chemin de la Vergognausaz 50, 1162 Saint-Prex, Switzerland

IMPORTED BY
PT Ferring Pharmaceuticals Industry
Tangerang Selatan – Indonesia

HARUS DENGAN RESEP DOKTER

REGISTRATION NO.: DKI2131800953A1

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Informasi untuk pasien
Pentasa 1 g supositoria
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 supositoria dan apa kegunaannya
2. Apa yang perlu Anda ketahui sebelum menggunakan PENTASA supositoria
3. Bagaimana cara pemberian PENTASA supositoria
4. Efek samping yang mungkin terjadi
5. Bagaimana cara penyimpanan PENTASA supositoria
6. Isi kemasan dan informasi lainnya

1. Apa itu PENTASA supositoria 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 proctitis ulserativa (radang hanya di rektum (lorong bagian belakang)).

2. Apa yang perlu Anda ketahui sebelum menggunakan PENTASA supositoria

Pastikan tidak mengalami dehidrasi ketika menggunakan obat ini. Hal ini dapat terjadi setelah berada pada kondisi muntah/dan atau diare berat atau parah, demam tinggi atau banyak berkeringat. Jika anda mengalaminya, segera hubungi dokter atau apoteker.

Jangan gunakan PENTASA supositoria:
- 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.

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– Dalam keadaan seperti itu Anda harus segera berhenti menggunakan 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 PENTASA supositoria
Beritahu dokter atau apoteker Anda jika Anda sedang menggunakan, baru-baru ini telah menggunakan atau mungkin akan 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 menggunakan 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 supositoria

Dosis yang dianjurkan adalah:
Orang dewasa:
1 supositoria 1-2 kali sehari.

Cara pemberian:
Kunjungan ke toilet dianjurkan sebelum pemberian supositoria. Produk atau limbah yang tidak terpakai harus dibuang sesuai dengan persyaratan lokal.
1. Letakkan salah satu pelindung jari pada satu jari.
2. Masukkan supositoria sejauh mungkin ke dalam rektum Anda.
3. Pemasangan mungkin lebih mudah jika Anda membasahi supositoria dengan air atau krim pelembab terlebih dahulu.
4. Jika tergelincir ke luar dalam waktu 10 menit, yang baru bisa dimasukkan sebagai gantinya.
5. Buang pelindung jari yang sudah bekas.

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Harus dimasukkan sampai lorong ke bagian belakang (rektum) saja. Itu dimaksudkan agar dapat tertinggal di situ selama mungkin dan oleh karena itu sebaiknya dimasukkan sesaat sebelum tidur.

Jika Anda menggunakan PENTASA lebih banyak daripada yang seharusnya
Jika terjadi overdosis, segera hubungi dokter atau departemen kedaruratan terdekat.

Jika Anda lupa menggunakan PENTASA
Jika Anda lupa menggunakan satu dosis, maka gunakan segera begitu Anda ingat, lalu gunakan dosis berikutnya pada waktu yang biasa. Jangan gunakan 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

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 lancar.

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

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) termasuk reaksi anafilaktik.
- 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

Proposed packaging material		
Code	PENSUP-I(PIL)-ID-05.01	
Size	N/A	
Submission	☐NDA ☐Renewal ☒Variation change detail : 220753	
Code of previous version	PENSUP-I(PIL)-ID-04.01	
Changes	CCDS Update v19	
Reference	☐CCDS version: ☒ Core PIL version: R-Core PIL-39734;Ver. 1.0, 02 Jan 2017	☐SPC country/version/date: ☐LAC no.:
Name & Date	HINI, 20 November 2025	

- kelainan ginjal (gejala termasuk darah dalam urin, dan/atau edema (pembengkakan akibat penumpukan cairan))
- perubahan warna urin
- gangguan pada sistem reproduksi: oligospermia (konsentrasi sperma dalam semen rendah)
- general disorder: demam
- lupus

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

Bagaimana cara penyimpanan PENTASA supositoria
Jauhkan obat ini dari pandangan dan jangkauan anak-anak.
Jangan gunakan obat ini setelah tanggal kadaluwarsa yang tercantum pada supositoria/foil. Tanggal kadaluwarsa mengacu pada hari terakhir bulan itu.

Simpan di bawah 30° C.
Simpan dalam kemasan asli.

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 supositoria
- Zat aktif : Mesalazine
- Eksipien lain : Magnesium stearat, talc, povidon, macrogol 6000

Seperti apa PENTASA supositoria dan bagaimana isi kemasannya
Supositoria berwarna putih sampai kecoklatan, bercak-bercak, berbentuk lonjong.
Supositoria dikemas dalam blister dobel aluminium foil, masing-masing berisi 7 supositoria.

PACKING SIZES
Double aluminium foil blisters. Box of 4 blisters x 7 suppositories. NIE DKIXXXXXXXXX

Pemegang Hak Pemasaran dan Produsen
Diproduksi oleh:
Ferring International Center SA Switzerland

Diimpor oleh:

Proposed packaging material		
Code	PENSUP-I(PIL)-ID-05.01	
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PT Ferring Pharmaceuticals Industry Tangerang Selatan-Indonesia

HARUS DENGAN RESEP DOKTER

Leaflet ini terakhir direvisi pada 20 November 2025.