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Size	NA	
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Changes	MA Transfer to Ferring	
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pCORTIMENT®
Budesonide
Prolonged release tablets 9 mg

QUALITATIVE AND QUANTITATIVE COMPOSITION
One tablet contains 9 mg of budesonide.

Excipients:
Tablet Core: Stearic Acid (E570), Lecithin (soya) (E322), Microcrystalline cellulose (E460), Hydroxypropylcellulose (E463), Lactose Monohydrate, Silica, Colloidal Hydrated (E551), Magnesium Stearate (E470b)
Tablet Film-coating: Methacrylic acid, Talc (E553b), Titanium Dioxide (E171), Triethyl citrate

PHARMACEUTICAL FORM
Prolonged release tablet.

White to off-white, round, biconvex, film-coated, gastro-resistant tablet, approximately 9.5 mm diameter, approximately 4.7 mm thickness, debossed on one side with “MX9”.

THERAPEUTIC INDICATIONS
Cortiment is indicated in adults for induction of remission in patients with mild to moderate active ulcerative colitis (UC) where 5-ASA treatment is not sufficient.

POSOLOGY AND METHOD OF ADMINISTRATION
The recommended daily dose for induction of remission is one 9 mg tablet in the morning, for up to 8 weeks.

Method of administration
One tablet of Cortiment 9 mg is taken orally in the morning, with or without food. The tablet should be swallowed with a glass of water and must not be broken, crushed or chewed as the film coating is intended to ensure a prolonged release.

CONTRAINDICATIONS
Hypersensitivity to the active substance, soya oil, peanut oil or to any of the listed excipients.

SPECIAL WARNINGS AND PRECAUTIONS FOR USE
Cortiment tablets should be used with caution in patients with infections, hypertension, diabetes mellitus, osteoporosis, peptic ulcer, glaucoma or cataracts or with a family history of diabetes or glaucoma or with any other condition where the use of glucocorticoids may have unwanted effects.

Visual disturbance may be reported with systemic and topical corticosteroid use. If a patient presents with symptoms such as blurred vision or other visual disturbances, the patient should be considered for referral to an ophthalmologist for evaluation of possible causes which may include cataract, glaucoma or rare diseases such as Central serous chorioretinopathy (CSCR) which have been reported after use of systemic and topical corticosteroids.

Reduced liver function may affect the elimination of glucocorticoids including budesonide, causing higher systemic exposure. Be aware of possible systemic side effects. Potential systemic effects include glaucoma.

When treatment is to be discontinued, it may be useful to gradually reduce the dose at the discretion of the treating physician.

Treatment with Cortiment tablets results in lower systemic steroid levels than conventional oral glucocorticoid therapy. Transfer from other steroid therapy may result in symptoms relating to the change in systemic steroid

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levels. Some patients may feel unwell in a non-specific way during the withdrawal phase, e.g., pain in muscles and joints. A general insufficient corticosteroid effect should be suspected if, in rare cases, symptoms such as tiredness, headache, nausea and vomiting should occur. In these cases a temporary increase in the dose of systemic corticosteroids is sometimes necessary.

As corticosteroids are known to have immunological effects the co-administration of Cortiment tablets is likely to reduce the immune response to vaccines.

Concomitant administration of ketoconazole or other potent CYP3A4 inhibitors should be avoided. If this is not possible, the period between treatments should be as long as possible and a reduction of the Cortiment dose could also be considered (see also section INTERACTION WITH OTHER MEDICINAL PRODUCTS AND OTHER FORMS OF INTERACTION). Following significant intake of grapefruit juice (which inhibits CYP3A4 activity predominantly in the intestinal mucosa), the systemic exposure for oral budesonide increased by approximately twofold. As with other drugs primarily being metabolised through CYP3A4, regular ingestion of grapefruit or grapefruit juice simultaneously with budesonide administration should be avoided (other juices such as orange juice or apple juice do not inhibit CYP3A4 activity). See also section INTERACTION WITH OTHER MEDICINAL PRODUCTS AND OTHER FORMS OF INTERACTION.

Cortiment tablets contain lecithin (soya oil). If a patient is hypersensitive to peanut or soya, this medicine should not be used.

Cortiment tablets contain lactose monohydrate and should not be taken by patients with rare hereditary problems such as galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption.

The following warnings and precautions have been generally identified for corticosteroids:

- Adrenocortical suppression has been observed when patients are transferred from systemic corticosteroid treatment with higher systemic effect.
- Suppression of the inflammatory response and immune system increases the susceptibility to infections.
- Corticosteroids may cause suppression of the HPA axis and reduce the stress response. Where patients are subject to surgery or other stresses, supplementary systemic corticosteroid treatment is recommended.
- Chicken pox and measles may follow a more serious course in patients on oral glucocorticoids. Particular care should be taken to avoid exposure in patients who have not previously had these diseases. If patients are infected or suspected of being infected, consider reduction or discontinuation of glucocorticosteroid treatment at the discretion of the treating physician.
- Systemic effects of steroids may occur, particularly when prescribed at high doses and for prolonged periods. Such effects may include Cushing's syndrome, adrenal suppression, growth retardation, decreased bone mineral density, cataract, glaucoma and very rarely a wide range of psychiatric/behavioural effects (see section UNDESIRABLE EFFECTS).
- Particular care is required when considering the use of systemic corticosteroids in patients with current or previous history of severe affective disorders in the patient or any first degree relatives. Replacement of high systemic effect corticosteroid treatment sometimes unmasks allergies, e.g. rhinitis and eczema that were previously controlled by the systemic drug.

INTERACTION WITH OTHER MEDICINAL PRODUCTS AND OTHER FORMS OF INTERACTION
No interaction studies have been performed.

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Budesonide is primarily metabolized by cytochrome P450 3A4 (CYP3A4). Inhibitors of this enzyme are e.g. ketoconazole, itraconazole, HIV protease inhibitors (including cobicistat-containing products) and grapefruit juice. Co-treatment with CYP3A inhibitors is expected to increase systemic exposure to budesonide several times and the risk of systemic side effects (see section SPECIAL WARNINGS AND PRECAUTIONS FOR USE). The combination should be avoided unless the benefit outweighs the increased risk of systemic corticosteroid side-effects, in which case patients should be monitored for systemic corticosteroid side-effects. If treatments are combined, the period between dosing of the combined treatments should be as long as possible and a reduction of the budesonide dose could also be considered. Budesonide is unlikely to inhibit other drugs metabolized via CYP3A4, since budesonide has low affinity to the enzyme.

Concomitant treatment with CYP3A4 inducers such as carbamazepine may reduce budesonide exposure, which may require a dose increase.

Corticosteroid interactions that may present a significant hazard to selected patients are those with heart glycosides (increased effect due to reduced potassium levels) and diuretics (increased elimination of potassium).

Increased plasma concentrations of and enhanced effects of corticosteroids have been observed in women also treated with oestrogens and contraceptive steroids, but no such effect has been observed with budesonide and concomitant intake of low-dose combination oral contraceptives.

Although not studied, concomitant administration of cholestyramine or antacids may reduce budesonide uptake, in common with other drugs. Therefore these preparations should not be taken simultaneously, but at least two hours apart.

At recommended doses, omeprazole does not affect the pharmacokinetics of oral budesonide, whereas cimetidine has a slight but clinically insignificant effect.

Because adrenal function may be suppressed, an ACTH stimulation test for diagnosing pituitary insufficiency might show false results (low values).

FERTILITY, PREGNANCY AND LACTATION

Pregnancy

Data on use of inhaled budesonide in a very large number of exposed pregnancies indicate no adverse effects. Although there are no data of outcomes of pregnancies after oral administration, the bioavailability after oral administration is low. In animal experiments, at high exposures, corticosteroids proved to be harmful (see section PRECLINICAL SAFETY DATA). Cortiment should only be used during pregnancy if the potential benefit justifies the potential risk to the fetus.

Breast-feeding

Budesonide is excreted in breast milk.

Maintenance treatment with inhaled budesonide (200 or 400 micrograms twice daily) in asthmatic nursing women results in negligible systemic exposure to budesonide in breast-fed infants.

In a pharmacokinetic study the estimated daily infant dose was 0.3% of the daily maternal dose for both dose levels, and the average plasma concentration in infants was estimated to be 1/600th of the concentrations observed in maternal plasma, assuming complete infant oral bioavailability.

Budesonide concentrations in infant plasma samples were all less than the limit of quantification.
Based on data from inhaled budesonide and the fact that budesonide exhibits linear PK properties within the therapeutic dosage intervals after inhaled, oral and rectal administrations, at therapeutic doses of budesonide, exposure to the suckling child is anticipated to be low. These data support continued use of budesonide, oral and rectal administrations, during breast-feeding.

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Fertility

There is no data on the effect of Cortiment on fertility in humans. There were no effects on fertility in rats after treatment with budesonide.

EFFECTS ON ABILITY TO DRIVE AND USE MACHINES
No studies on the effects of Cortiment on the ability to drive and use machines have been performed. When driving vehicles or using machines it should be taken into account that occasionally dizziness or tiredness may occur (see section UNDESIRABLE EFFECTS).

UNDESIRABLE EFFECTS
Adverse drug reactions reported in clinical trials with Cortiment are presented in Table 1. Adverse drug reactions reported for the therapeutic class are presented in Table 2. In Phase II and III clinical trials, the incidence of adverse events for Cortiment tablets, at the recommended dose of 9 mg/day, was comparable to placebo. Most adverse events were of mild to moderate intensity and of a non-serious nature.

Adverse reactions reported are listed according to the following frequency: Very common (≥ 1/10); common (≥ 1/100 to < 1/10); uncommon (≥ 1/1,000 to < 1/100); rare (≥ 1/10,000 to < 1/1,000); very rare (< 1/10,000).

Table 1 Cortiment drug-related adverse reactions reported during clinical trials with more than one case (N=255)

MedDRA System Organ Classification	**Preferred Term of Adverse Drug Reaction**	
	Common	**Uncommon**
Infections and infestations		Influenza
Blood and lymphatic system disorders		Leukocytosis
Psychiatric disorders	Insomnia	Mood altered
Nervous system disorders	Headache	Dizziness
Gastrointestinal disorders	Nausea Abdominal pain upper Abdominal distension Abdominal pain Dry mouth Dyspepsia	Flatulence
Skin and subcutaneous tissue disorders	Acne	
Musculoskeletal and connective tissue disorders	Myalgia	Back pain Muscle spasms
General disorders and administration site conditions	Fatigue	Oedema peripheral
Investigations	Blood cortisol decreased	

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Table 2 Events reported for the therapeutic class (intestinal anti-inflammatory agents, corticosteroids acting locally, budesonide)

MedDRA System Organ Classification	Common	Uncommon	Rare	Very Rare
Immune system disorders				Anaphylactic reaction
Endocrine disorders	Cushingoid features			Growth retardation in children*
Metabolism and nutrition disorders	Hypokalemia			
Psychiatric disorders	Behavioural changes such as nervousness, insomnia and mood swings Depression	Psychomotor hyperactivity Anxiety	Aggression	
Nervous system disorders		Tremor		
Eye disorders			Cataract including subcapsular cataract Glaucoma Vision, blurred	
Cardiac disorders	Palpitations			
Gastrointestinal disorders	Dyspepsia			
Skin and subcutaneous tissue disorders	Skin reactions (urticaria, exanthema)		Ecchymosis	
Musculoskeletal and connective tissue disorders	Muscle cramps			
Reproductive system and breast disorders	Menstrual disorders			

* Note that Cortiment is not recommended for use in children (see 4.2)
Most of the adverse events mentioned in this leaflet can also be expected for other treatments with glucocorticoids.

Side effects typical of systemic corticosteroids (e.g. cushingoid features and growth retardation) may occur. These side effects are dependent on dose, treatment time, concomitant and previous corticosteroid intake, and individual sensitivity.

Paediatric population
No data available.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product.
Healthcare professionals are asked to report any suspected adverse reactions via <the national reporting system> <[to be completed nationally]>.

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OVERDOSE

Due to the low systemic availability of Cortiment tablets, acute overdosage even at very high doses is not expected to lead to an acute clinical crisis. In the event of acute overdosage, no specific antidote is available. Treatment consists of supportive and symptomatic therapy.

PHARMACODYNAMIC PROPERTIES

Pharmacotherapeutic group: Intestinal anti-inflammatory agents, Corticosteroids acting locally

ATC code: A07E A06

Mechanism of action

The exact mechanism of action of budesonide in the treatment of UC is not fully understood. In general, budesonide inhibits many inflammatory processes including cytokine production, inflammatory cell activation and expression of adhesion molecules on endothelial and epithelial cells. At doses clinically equivalent to prednisolone, budesonide gives significantly less HPA axis suppression and has a lower impact on inflammatory markers.

Data from clinical pharmacology and pharmacokinetic studies indicate that the mode of action of Cortiment tablets is based on a local action in the gut.

Pharmacodynamic effects

MMX extended release technology is characterised by a multi-matrix structure covered by a gastro-resistant coating that dissolves in intestinal fluids having a pH greater than 7.
When the dosage form is administered, the gastro-protective layer protects the dosage form during transit through the stomach and duodenum up to the lower part of the intestine. When the protective layer is lost, the intestinal fluid then comes into contact with the hydrophilic matrix polymers, which start to swell until a viscous gel matrix is formed. The solvent that penetrates into the gel matrix dissolves the active ingredient from the lipophilic matrices. Budesonide is then released into the intestinal tract at a controlled rate throughout the colon.

Budesonide is a glucocorticoid used in the treatment of inflammatory bowel disease. It has a topical anti-inflammatory activity, but does not reduce cortisol levels to the same extent as systemic glucocorticoids.

Clinical efficacy

Two randomised, controlled phase III clinical trials including 1022 patients with mild to moderate active UC have been performed in adult patients. Two hundred fifty five (255) patients were treated for 8 weeks with Cortiment 9 mg per day. Patients included were either treatment naïve (42% ITT) or had failed on 5-ASA (58% ITT). Both studies included a reference arm, mesalazine (Asacol) and budesonide (Entocort), respectively to show assay sensitivity. The definition of remission applied in both studies was UCDAI score of ≤1, with 0 score for rectal bleeding and stool frequency, normal mucosa (no friability) and ≥1 point reduction in endoscopy score.

Effect of Cortiment 9mg tablet on Primary Endpoint:

Study	Cortiment 9 mg Remission (%)	Placebo Remission (%)	P=
Study CB-01-02/01	17.9	7.4	0.0143
Study CB-01-02/02	17.4	4.5	0.0047

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Statistical difference versus placebo was reached for Cortiment 9 mg for both studies and the difference versus placebo was 10.4% and 12.9% respectively.

5-ASA is the Standard of Care for treatment of mild to moderate disease. Results of a head to head comparison with Cortiment and 5-ASA were not available. Therefore, the place in the therapeutic work-up remains to be established. Some patients may benefit from treatment initially with Cortiment.

Paediatric Population

Cortiment was not studied in the paediatric population.

PHARMACOKINETIC PROPERTIES

Absorption

After oral dosing of plain micronised compound, absorption seems to be complete. A large proportion of the unformulated drug is absorbed from the ileum and ascending colon.

Systemic availability of Budesonide following a single administration of Cortiment tablets in healthy volunteers was compared to that of Entocort and the result was similar, about 10%, due to first pass metabolism in the liver. Maximum plasma concentrations of budesonide are approximately 1.3-1.8 ng/ml at 13-14 hours post administration. Concomitant administration of Cortiment tablets with food had no clinically relevant effect on absorption. It has been shown that there is no potential for drug accumulation on repeated dosing.

Distribution

Budesonide has a high volume of distribution (about 3 L/kg). Plasma protein binding averages 85–90%.

Biotransformation

Budesonide undergoes extensive biotransformation in the liver to metabolites of low glucocorticoid activity. The glucocorticoid activity of the major metabolites, 6β-hydroxybudesonide and 16α-hydroxy-prednisolone, is less than 1% of that of budesonide. The metabolism of budesonide is primarily mediated by CYP3A, a subfamily of cytochrome P450.

Elimination

Elimination of budesonide is rate limited by absorption. Budesonide has a high systemic clearance (about 1.2 L/min).

Paediatric Population

No data or experience is available with respect to the pharmacokinetics of Cortiment tablets in the paediatric population.

PRECLINICAL SAFETY DATA

A preclinical toxicology and toxicokinetic bridging study, comparing Cortiment tablets with an existing prolonged release budesonide formulation (Entocort® EC 3 mg capsules, AstraZeneca) in cynomolgous monkeys has confirmed that Cortiment tablets result in a delayed peak exposure and reduced total exposure compared to the existing formulation of budesonide, while maintaining a superimposable toxicological profile.

Preclinical data have shown that budesonide produces effects less severe or similar to other glucocorticoids, such as weight increase, atrophy of the adrenal glands and thymus and effects on the leucocyte count. As with other glucocorticosteroids, and dependent on the dose and duration and the diseases concerned, these steroid effects may also be relevant in man.

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Budesonide had no effect on fertility in rats. In pregnant rats and rabbits, budesonide, like other glucocorticosteroids, has been shown to cause foetal death and abnormalities of foetal development (smaller litter size, intrauterine foetal growth retardation and skeletal abnormalities). Some glucocorticoids have been reported to produce cleft palate in animals. The relevance of these findings to man has not been established (see also section FERTILITY, PREGNANCY AND LACTATION).

Budesonide had no mutagenic effects in a number of in vitro and in vivo tests. A slightly increased number of basophilic hepatic foci were observed in chronic rat studies with budesonide, and in carcinogenicity studies an increased incidence of primary hepatocellular neoplasms, astrocytomas (in male rats) and mammary tumours (in female rats) were observed. These tumours are probably due to the specific steroid receptor action, increased metabolic burden and anabolic effects on the liver, effects which are also known from rat studies with other glucocorticosteroids and therefore represent a class effect in this species.

INCOMPATIBILITIES
Not applicable.

SHELF LIFE
2 years.

STORAGE
Store below 30°C.

SPECIAL PRECAUTIONS FOR DISPOSAL AND OTHER HANDLING
Any unused medicinal product or waste materials should be disposed of in accordance with local requirements.

PACKING SIZE
Box of 3 blisters @ 10 prolonged release tablets (Reg. No.: DKI XXXXXXXXXXX)

MANUFACTURED BY
Cosmo SpA
Milan, Italy

IMPORTED BY
PT Ferring Pharmaceuticals Industry
Tangerang Selatan – Indonesia

HARUS DENGAN RESEP DOKTER

DATE OF REVISION
26 August 2021

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Informasi untuk pasien
Cortiment 9 mg tablet lepas lambat
Budesonide

Bacalah seluruh isi leaflet ini dengan seksama sebelum Anda mulai meminum obat ini karena leaflet ini berisi informasi penting untuk Anda.
- Simpanlah leaflet ini, sebab Anda mungkin perlu membacanya lagi dikemudian hari.
- Apabila Anda memiliki pertanyaan lebih lanjut, tanyakan pada dokter, bidan atau perawat Anda.
- Obat ini telah diresepkan untuk Anda saja. Jangan berikan kepada orang lain karena dapat membahayakan mereka, walaupun tanda-tanda penyakit mereka sama dengan Anda.
- Jika Anda mendapat efek samping, bicarakan dengan dokter Anda, termasuk efek samping yang mungkin tidak tercantum dalam brosur ini. Lihat bagian 4.

Apa yang ada di leaflet ini?

1. Apa CORTIMENT itu dan digunakan untuk apa

Tablet CORTIMENT mengandung obat yang disebut budesonide. Budesonide termasuk dalam kategori 'kortikosteroid', yang digunakan untuk mengurangi peradangan.
Tablet CORTIMENT digunakan untuk orang dewasa untuk pengobatan radang usus besar (kolon) dan rektum. Ini disebut kolitis ulserativa.

2. Apa yang perlu Anda ketahui sebelum Anda meminum CORTIMENT

Jangan meminum CORTIMENT:
- Jika Anda alergi terhadap budesonide atau salah satu dari bahan tambahan dari obat ini (tercantum dalam bagian 6).
- Jika Anda alergi terhadap kacang atau kedelai karena CORTIMENT mengandung lesitin, yang merupakan turunan dari minyak kedelai.

Peringatan dan tindakan pencegahan
Hubungi dokter Anda jika Anda mengalami penglihatan kabur atau gangguan visual lainnya.
Bicarakan dengan dokter Anda sebelum meminum CORTIMENT:
- jika Anda memiliki infeksi, seperti infeksi virus, infeksi bakteri atau infeksi jamur;
- jika Anda pernah memiliki tekanan darah tinggi;
- jika Anda menderita diabetes;
- jika Anda pernah memiliki tulang rapuh;
- jika Anda pernah mengalami sakit maag;
- jika Anda pernah mengalami tekanan bola mata tinggi (glaukoma) atau katarak abu-abu;

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- jika seorang anggota keluarga pernah menderita diabetes atau tekanan bola mata tinggi (glaukoma);
- jika Anda pernah memiliki masalah liver;
- jika Anda berpindah dari terapi cortisone lain ke CORTIMENT karena ini dapat mengakibatkan mis. nyeri pada otot dan sendi, kelelahan, sakit kepala, mual, dan muntah;
- jika Anda tahu bahwa Anda perlu divaksinasi;
- jika Anda telah diobati dengan sediaan kortison yang lebih kuat sebelum memulai pengobatan CORTIMENT, gejala Anda mungkin akan muncul kembali;
- jika Anda mendapatkan infeksi selama pengobatan, CORTIMENT dapat menyembunyikan tanda-tanda infeksi dan infeksinya bisa memburuk. Anda mungkin mendapatkan infeksi lebih mudah selama pengobatan dengan CORTIMENT, karena ketahanan tubuh Anda terhadap infeksi dapat berkurang;
- jika Anda dijadwalkan untuk segera menjalani operasi atau akan mengalami haid yang cukup banyak;
- jika Anda belum pernah mengalami cacar atau cacar air. Saat meminum tablet CORTIMENT, cobalah untuk menghindari orang-orang dengan campak atau cacar air. Beritahu dokter Anda jika Anda pikir Anda telah terinfeksi cacar air atau campak saat meminum obat ini.
- jika Anda atau anggota keluarga dekat menderita masalah dengan kesehatan mental.

Meminum preparat kortison pada dosis tinggi dan untuk periode yang lama dapat mempengaruhi seluruh bagian tubuh dan dalam kasus yang sangat jarang terjadi dapat memberikan masalah psikologis (lihat bagian 4. Efek samping yang mungkin terjadi).

Jika Anda memiliki keraguan tentang apakah salah satu dari hal di atas berlaku untuk Anda, hubungi dokter Anda sebelum Anda meminum tablet CORTIMENT.

Obat-obat lain dan CORTIMENT
Katakan kepada dokter Anda jika Anda sedang meminum, baru saja meminum atau mungkin akan meminum obat lain, termasuk obat-obat yang diperoleh tanpa resep. Ini diperlukan karena tablet CORTIMENT memengaruhi cara kerja beberapa obat lain dan beberapa obat lain dapat mempengaruhi cara kerja CORTIMENT. Beberapa obat lain dapat meningkatkan efek CORTIMENT dan dokter Anda mungkin ingin memantau Anda secara seksama jika Anda meminum obat-obat tersebut (termasuk beberapa obat untuk HIV; ritonavir, cobicistat).

Terutama sangatlah penting bahwa Anda memberi tahu dokter jika Anda sedang meminum, baru-baru ini meminum atau mungkin akan meminum salah satu obat berikut:
- ketoconazole atau itraconazole, yang merupakan obat yang digunakan untuk mengobati infeksi jamur;
- obat-obat yang digunakan untuk pengobatan HIV (misalnya ritonavir, nelfinavir, produk yang mengandung cobicistat);
- carbamazepine, yang digunakan untuk pengobatan epilepsi;
- glikosida jantung dan diuretik;
- obat-obat yang mengandung estrogen, seperti terapi pengganti hormon (HRT) dan beberapa pil KB;
- cholestyramine, yang digunakan untuk menurunkan kadar kolesterol atau mengobati gatal yang disebabkan oleh liver
- masalah-masalah, atau antasida yang digunakan untuk menetralisir asam yang dibuat oleh perut Anda.

CORTIMENT dengan makanan, minuman dan alkohol
Jangan minum jus grapefruit saat mengonsumsi tablet CORTIMENT. Ini dapat mempengaruhi cara kerja obat.

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Kehamilan, menyusui dan kesuburan
Jika Anda sedang hamil atau menyusui, mengira Anda mungkin sedang hamil atau berencana untuk punya anak, mintalah saran dokter Anda sebelum meminum obat ini.

Berkendara dan mengoperasikan mesin
Kemungkinan besar CORTIMENT tidak akan mempengaruhi kemampuan Anda dalam berkendara dan menjalankan mesin. Kehati-hatian diperlukan karena jenis obat ini kadang-kadang dapat menyebabkan pusing atau kelelahan.

CORTIMENT mengandung laktosa dan lesitin (minyak kedelai)
Tablet CORTIMENT mengandung laktosa, sejenis gula. Jika Anda pernah diberitahu oleh dokter Anda bahwa Anda memiliki intoleransi terhadap beberapa gula, hubungi dokter Anda sebelum meminum produk obat ini.

CORTIMENT mengandung lecithin (minyak kedelai). Jika Anda alergi terhadap kacang atau kedelai, jangan gunakan produk obat ini.

3. Bagaimana cara meminum CORTIMENT

Selalu minum obat ini persis seperti yang dikatakan oleh dokter Anda. Periksakan ke dokter Anda jika Anda tidak yakin.
- Dosis yang dianjurkan adalah satu tablet di pagi hari sebelum atau bersamaan dengan sarapan.
- Telan tablet utuh-utuh dengan segelas air; tablet tidak boleh dipecahkan, dihancurkan atau dikunyah.
- Biasanya Anda meminum obat ini setiap hari selama maksimal delapan minggu. Dokter Anda mungkin secara bertahap akan mengurangi jumlah berapa kali Anda minum obat.
- Tetap minum tablet CORTIMENT seperti yang dikatakan dokter Anda, meskipun Anda mulai merasa lebih baik.

Informasi tambahan saat meminum tablet CORTIMENT
Jika Anda akan segera menjalani operasi atau sedang mendapatkan haid yang berat, dokter mungkin meminta Anda untuk mengonsumsi tablet steroid lain juga.

Penggunaan pada pasien dengan penurunan fungsi ginjal atau liver
CORTIMENT tidak diselidiki secara khusus pada pasien dengan masalah ginjal atau liver. Bicarakan dengan dokter Anda.

Penggunaan pada anak-anak
Tablet CORTIMENT tidak direkomendasikan untuk digunakan pada anak-anak.

Jika Anda meminum CORTIMENT lebih banyak dari yang seharusnya
Jika Anda mengonsumsi tablet CORTIMENT lebih banyak dari yang seharusnya, segera hubungi dokter Anda.

Jika Anda lupa untuk meminum CORTIMENT
- Jika Anda lupa untuk meminum tablet CORTIMENT, minumlah segera begitu Anda ingat. Jika sudah hampir waktunya untuk dosis berikutnya, lewati saja dosis yang sudah terlewat.
- Jangan meminum dosis dobel untuk mengganti tablet yang terlupakan.

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Jika Anda berhenti mengonsumsi CORTIMENT
Jangan berhenti mengonsumsi tablet CORTIMENT tanpa membicarakannya dengan dokter Anda terlebih dahulu. Anda mungkin perlu menghentikan pengobatan secara bertahap. Jika Anda tiba-tiba berhenti minum obat, Anda mungkin menjadi sakit.
Jika Anda memiliki pertanyaan lebih lanjut tentang penggunaan obat ini, tanyakan kepada dokter Anda.

4. Efek samping yang mungkin terjadi

Seperti semua obat lainnya, obat ini dapat menyebabkan efek samping, meskipun tidak semua orang mendapatkannya.

Jika Anda mendapatkan reaksi alergi, segera hubungi dokter Anda. Tanda-tandanya dapat berupa gatal-gatal atau bengkak pada wajah, bibir, mulut, lidah dan tenggorokan. Ini bisa membuat sulit bernapas.

Efek samping berikut dapat terjadi ketika meminum CORTIMENT; sebagian besar efek samping yang disebutkan di bawah ini juga dapat diharapkan terjadi dengan pengobatan steroid lainnya.

Umum (dapat mengenai hingga 1 dari 10 orang)
- Gejala seperti cushing, seperti wajah bulat, jerawat, berat badan naik dan kecenderungan untuk memar dengan mudah
- Kadar potasium rendah dalam darah, yang dapat menyebabkan kelemahan atau kelelahan otot, rasa haus atau terasa kesemutan
- Perubahan perilaku, seperti gugup, insomnia dan perubahan suasana hati
- Depresi
- Sakit kepala
- Detak jantung yang keras (palpitasi)
- Mual
- Sakit perut
- Perut kembung
- Mulut kering
- Gangguan pencernaan (dispepsia)
- Ruam kulit atau gatal
- Jerawat
- Nyeri otot, kram otot
- Haid berat atau tidak teratur pada wanita
- Kelelahan ekstrim (kelelahan)
- Penurunan hormon kortisol dalam darah

Tidak umum (dapat mengenai hingga 1 dari 100 orang)
- Influenza
- Peningkatan sel darah putih
- Perubahan perilaku, seperti perubahan suasana hati
- Merasa gelisah dengan hiperaktivitas
- Kecemasan
- Pusing
- Gemetar
- Perut kembung

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- Nyeri punggung
- Kejang otot
- Pembengkakan kaki

Jarang (dapat mengenai hingga 1 dari 1.000 orang)
- Agresi
- Glaukoma (peningkatan tekanan di mata)
- Opasitas lensa atau kapsul mata (katarak)
- Penglihatan kabur
- Bintik ungu atau hitam-biru pada kulit

Sangat jarang (dapat mengenai hingga 1 dari 10.000 orang)
- Reaksi alergi yang serius (disebut anafilaksis) yang dapat menyebabkan kesulitan bernapas dan potensi syok
- Pertumbuhan yang lambat pada anak-anak

Beberapa efek samping yang disebutkan di atas adalah khas untuk obat steroid dan dapat terjadi tergantung pada dosis Anda, masa pengobatan, apakah Anda telah atau pernah menjalani perawatan dengan preparat kortison lainnya, dan kerentanan individu Anda.
Masalah psikologis dapat berkembang ketika meminum steroid seperti CORTIMENT. Diskusikan dengan dokter Anda jika Anda (atau seseorang yang menggunakan obat ini) mengalami gejala masalah psikologis.
Ini terutama sangat penting jika Anda depresi dan mungkin berpikir untuk bunuh diri. Dalam kasus yang sangat jarang, masalah psikologis telah berkembang ketika dosis tinggi diminum untuk waktu yang lama.

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 Distribusi Produk Terapetik dan PKRT 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 dan Indonesia-MESO-BadanPOM@hotmail.com

5. Bagaimana cara menyimpan CORTIMENT

Jauhkan obat ini dari pandangan dan jangkauan anak-anak.
Jangan gunakan obat ini setelah tanggal kadaluwarsa yang tercantum pada karton dan pada kemasan blister setelah EXP. Tanggal kadaluwarsa mengacu pada hari terakhir bulan tersebut.
Simpan di bawah 30° C.
Jangan membuang obat apa pun melalui air limbah atau limbah rumah tangga. Tanyakan apoteker Anda bagaimana membuang obat-obat yang tidak lagi Anda gunakan. Langkah-langkah ini akan membantu melindungi lingkungan.

6. Isi kemasan dan informasi lainnya

Apa isi CORTIMENT
- Zat aktif dalam obat ini adalah budesonide. Tiap tablet mengandung 9 mg budesonide.

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- Bahan lain (eksipien) dalam obat ini adalah:

inti tablet: asam stearat (E570), lecithin (kedelai) (E322), selulosa mikrokristalin (E460), hidroksipropilselulosa (E463), laktosa monohidrat, silika koloid terhidrasi (E551), magnesium stearat (E470b)
lapisan selaput: methacrylic acid-methyl methacrylate copolymer (1: 1), methacrylic acid-methyl methacrylate copolymer (1: 2), talc (E553b), titanium dioxide (E171), triethyl citrate

Seperti apa bentuk CORTIMENT dan isi kemasannya
CORTIMENT disediakan sebagai tablet warna putih sampai putih mangkak, bundar, cembung ganda dengan lapisan selaput, dan terukir 'MX9' di satu sisi tablet. Tablet ini disediakan dalam kemasan blister dengan aluminium press-through foil dalam karton kardus.
Obat ini tersedia dalam kemasan 30 tablet.

Pemegang Hak Pemasaran dan Produsen
Cosmo SpA
Milan, Italy

Diimpor oleh:
PT Ferring Pharmaceuticals Industry
Tangerang Selatan – Indonesia

HARUS DENGAN RESEP DOKTER

Leaflet ini terakhir direvisi pada 26 Agustus 2021.