Ratiopharm logo
Package leaflet: Information for the user

Cotrim E-ratiopharm®
480 mg/5 mL syrup

Active substance: sulfamethoxazole 400 mg and trimethoprim 80 mg

Read all of this leaflet carefully before you start taking this medicine.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

In this leaflet:
1. What Cotrim E-ratiopharm® 480 mg/5 mL is and what it is used for
2. Before you take Cotrim E-ratiopharm® 480 mg/5 mL
3. How to take Cotrim E-ratiopharm® 480 mg/5 mL
4. Possible side effects
5. How to store Cotrim E-ratiopharm® 480 mg/5 mL
6. Further information

1. What Cotrim E-ratiopharm® 480 mg/5 mL is and what it is used for

Cotrim E-ratiopharm® 480 mg/5 mL is a combination of two active substances that block the metabolism of folic acid (a water-soluble vitamin) in susceptible pathogens (disease-causing germs).

Cotrim E-ratiopharm® 480 mg/5 mL is used to treat infections (contagious diseases) caused by pathogens susceptible to trimethoprim/sulfamethoxazole and which are amenable to oral treatment:
- infections of the upper and lower airways
- pneumonia caused by Pneumocystis jiroveci (PCP)
- infections of the ear, nose and throat region (except streptococcal tonsillitis)
- infections of the kidney and lower urinary tract (bladder, urethra) including long-term treatment to prevent a relapse
- infections of the female and male sexual organs, including prostatitis (prostate inflammation) and granuloma venereum (a chronic sexual disease) (syphilis is not included)
- infections of the gastrointestinal tract:
  - shigellosis (bacterial dysentery), travellers’ diarrhoea, chronic typhoid carriers
  - For the following infections, co-trimoxazole (sulfamethoxazole and trimethoprim) should only be used when other currently recommended antibiotics cannot be given: typhoid, paratyphoid A and B, salmonella diarrhoea (salmonella enteritis) progressing to septic disorders (high fever after the bacteria have penetrated the bloodstream), in newborn babies, infants and patients with a weakened immune system
- brucellosis (a contagious disease transmitted by house pets)
- nocardiosis (a contagious disease mainly affecting patients with a weakened immune system)
- pseudofungal mycetoma (a tumour caused by bacteria)
- South American blastomycosis (a fungal skin disease)

Note:
Gastrointestinal inflammation caused by microbes known as “enteric fever salmonellae” should generally not be treated with Cotrim E-ratiopharm® 480 mg/5 mL, as the progression of disease is not affected and the duration of excretion may even be prolonged (exception, see above).

2. **Before you take Cotrim E-ratiopharm® 480 mg/5 mL**

**Do not use Cotrim E-ratiopharm® 480 mg/5 mL**
- if you are allergic (hypersensitive) to sulphonamide agents, trimethoprim and related agents (trimethoprim analogues, e.g. tetroxoprim), methylhydroxybenzoate (Ph.Eur.), propylhydroxybenzoate (Ph.Eur.) or any of the other ingredients of Cotrim E-ratiopharm® 480 mg/5 mL
- if you have erythema exsudativum multiforme (a severe disease with redness and blistering of the skin), or if you have ever had this condition
- if you have any pathological, abnormal blood counts (decrease in blood platelets or certain white blood cells, a certain type of anaemia)
- if you have certain red blood cell disorders (congenital glucose-6-phosphate dehydrogenase deficiency and haemoglobin abnormalities such as Hb Köln or Hb Zurich)
- if you have kidney damage or severely impaired kidney function
- if you have severe liver damage or your liver function (e.g. in acute hepatitis) is impaired
- if you are suffering from acute porphyria (problems in haemoglobin formation)
- in premature infants
- in newborn infants with hyperbilirubinaemia (high blood levels of bilirubin, a bile pigment) or with glucose-6-phosphate dehydrogenase deficiency, a condition affecting the red blood cells.
- if you have osteomyelitis (bone marrow inflammation). This condition is mostly caused by pathogens in which the effect of Cotrim E-ratiopharm® 480 mg/5 mL is often inadequate. For this reason, Cotrim E-ratiopharm® 480 mg/5 mL must not be used for this condition.

**Take special care with Cotrim E-ratiopharm® 480 mg/5 mL**
- if you are allergic (hypersensitive) to sulphonamide-like medicines used to treat diabetes (sulphonylurea antidiabetics) and as water tablets (sulphonamide-based diuretics)
- if you have a milder form of kidney or liver dysfunction
- if your thyroid function is impaired
- if you might have folic acid deficiency (a vitamin important in blood formation, for instance)
- if you have a certain hereditary disorder (fragile X chromosome in combination with poor mental development in children)
- in newborn infants up to 5 weeks of age.

Severe skin reactions (Stevens-Johnson syndrome, toxic epidermal necrolysis), which may be life-threatening, have been reported in association with the use of Cotrim E-ratiopharm® 480 mg/5 mL. These initially appear as reddish, target-like or circular patches (often with a blister in the centre) on the trunk of the body. The rash can lead to extensive blistering or peeling of the skin. Additional symptoms to look out for are open, painful sites (ulcers) in the mouth, throat, nose and in the genital area, as well as red and puffy eyes (conjunctivitis). These potentially life-threatening skin reactions are often accompanied by flu-like symptoms (headache, fever and aching limbs). The risk of experiencing this severe skin reaction is greatest within the first few weeks of treatment.
If you have experienced Stevens-Johnson syndrome or toxic epidermal necrolysis associated with the use of Cotrim E-ratiopharm® 480 mg/5 mL, you must never again be treated with Cotrim E-ratiopharm® 480 mg/5 mL.

If you develop a rash or any of the other skin symptoms mentioned, stop using Cotrim E-ratiopharm® 480 mg/5 mL and consult a doctor immediately. Tell him/her that you are taking Cotrim E-ratiopharm® 480 mg/5 mL.

Patients with phenylketonuria (a disease caused by a defect in phenylalanine metabolism) who are on a strict low phenylalanine diet can take Cotrim E-ratiopharm® 480 mg/5 mL.

In cases of impaired kidney and liver function, thyroid dysfunction and possible folic acid deficiency, the use of Cotrim E-ratiopharm® 480 mg/5 mL requires strict medical surveillance.

In patients receiving an active substance called ciclosporin (a substance used to suppress the body's immune system) after a kidney transplant, there is an increased harmful effect on the kidneys during treatment with Cotrim E-ratiopharm® 480 mg/5 mL. For this reason, Cotrim E-ratiopharm® 480 mg/5 mL should not be used as a first choice in kidney transplant patients with urinary tract infections.

Flu-like symptoms, sore throat or fever may be signs of abnormal blood counts. If these signs occur, blood counts must be checked immediately.

In patients with AIDS, the frequency of side effects (especially skin hypersensitivity reactions with varying degrees of severity) is extraordinarily high, due to the high amounts of medicine required to treat Pneumocystis pneumonia.

In these patients, blood levels of the active substances in Cotrim E-ratiopharm® 480 mg/5 mL must be measured, as urinary excretion of these substances may be severely impaired, even though measurements of kidney function are normal.

Salt imbalances in the blood (low potassium levels, high potassium levels together with low sodium levels) have occurred. For this reason, blood potassium and sodium levels must be closely monitored during treatment, especially at the start of treatment and if kidney function is impaired.

During treatment with Cotrim E-ratiopharm® 480 mg/5 mL, adequate hydration (adults; urine output of at least 1 200 mL per day) must be ensured.

Photosensitisation (development of skin reactions after exposure to light) can occur in patients taking Cotrim E-ratiopharm® 480 mg/5 mL. This should particularly be taken into account in cases of exposure to strong sunlight and UV light.

In elderly patients, in patients with folic acid deficiency and when administering high doses of Cotrim E-ratiopharm® 480 mg/5 mL, folic acid administration should be considered.

All use of antibiotics can lead to an increase in pathogens which are insensitive (resistant) to the medicine being used.

You must consult your doctor if severe, persistent, sometimes bloody/mucous diarrhoea and cramp-like abdominal pain occur during or after treatment with Cotrim E-ratiopharm® 480 mg/5 mL, as this may be masking serious and severe inflammation of the bowel lining (pseudomembranous
colitis) – usually caused by *Clostridium difficile* – which must be treated immediately. This bowel
disease, triggered by antibiotic treatment, can be life-threatening.

In patients born with erythrocyte glucose-6-phosphate dehydrogenase deficiency (lack of a sugar
metabolism enzyme) or with haemoglobin (red blood pigment) abnormalities such as *Hb Köln* and
*Hb Zurich*, cyanosis (purple discoloration of the skin and mucous membranes) may occur due to
sulph- or methaemoglobinaemia (changes in the red blood pigment). In sensitive patients with
glucose-6-phosphate dehydrogenase deficiency, haemolysis (disintegration of red blood cells) may
be triggered, regardless of the dose.

**Long-term administration or use of high doses**
If Cotrim E-ratiopharm® 480 mg/5 mL is administered for more than 14 days, regular blood count
monitoring (particularly the platelet count) is required.

After 1 month of maintenance treatment, there have been indications of impaired spermatogenesis
(sperm development) in men.

Prolonged and/or repeated use of Cotrim E-ratiopharm® 480 mg/5 mL can lead to new or
secondary infections with bacteria or yeast-like fungi not susceptible (resistant) to
trimethoprim/sulfamethoxazole.

Vigilance is required for signs of possible secondary infection with such pathogens (e.g. fungal
infection of the mucous membranes, with redness and a whitish coating on the mucous
membranes). Secondary infections must be treated accordingly.

**Children**
Cotrim E-ratiopharm® 480 mg/5 mL is suitable for use in children, although not for infants under
6 weeks of age. For children under 6 years and infants, a formulation with a lower active substance
content is also available.

**Elderly**
In elderly patients, the use of Cotrim E-ratiopharm® 480 mg/5 mL requires strict medical
surveillance.

**Other medicines and Cotrim E-ratiopharm® 480 mg/5 mL**
Please tell your doctor or pharmacist if you are taking/using or have recently taken/using any other
medicines, including medicines obtained without a prescription.

The use of Cotrim E-ratiopharm® 480 mg/5 mL with other medicines can lead to interactions,
particularly with use of:
- certain medicines to reduce stomach acid (mineral antacids)
- paraldehyde (sleep medication)
- para-aminobenzoic acid derivatives (group of active substances for local anaesthesia, e.g.
  benzocaine, procaine, butacaine and tetracaine)
- procaainamide (medicine for irregular heartbeat)
- probenecid and sulfispyrazone (medicines to treat high uric acid levels)
- indomethacin (medicine to treat pain, rheumatism and inflammation)
- phenylbutazone (medicine to treat gout and certain rheumatic diseases)
- salicylates (group of medicines to treat fever, inflammation and to prevent blood clotting)
- p-aminosalicylic acid (medicine to treat tuberculosis)
- barbiturates (sleep medication)
- primidone (medicine to treat seizures)
- methenamine
- pyrimethamine (medicine to treat various conditions, including malaria and toxoplasmosis)
- medicines that also cause folic acid deficiency (e.g. methotrexate)
- medicines also actively excreted via the kidneys (e.g. procainamide [medicine to treat irregular heartbeat] or amantadine [an antiviral agent])
- ciclosporin (medicine to suppress the body’s own immune system)
- 6-mercaptopurin
- rifampicin (medicine for tuberculosis)
- coumarins (medicines to prevent blood clotting)
- certain medicines for high blood sugar (oral sulphonylurea antidiabetics)
- diphenylhydantoin (phenytoin, medicine to treat seizures), methotrexate (medicine to treat cancer)
- short-acting, intravenously administered barbiturates (medicines for anaesthesia, e.g. thiopental)
- certain medicines for poor heart function (increased digoxin levels) in elderly patients
- folic acid in the treatment of megaloblastic anaemia (a certain type of blood deficiency)
- hormonal contraceptives (the “Pill”): The use of extra non-hormonal forms of contraception is therefore recommended.

**Pregnancy and breast-feeding**

During pregnancy, Cotrim E-ratiopharm® 480 mg/5 mL should only be used after careful benefit/risk assessment. Although experience to date has shown no evidence of any increased risk of malformation in humans, such a risk might exist due to the effect on folic acid metabolism. For newborn infants exposed before childbirth (especially premature infants), there is a particular risk of hyperbilirubinaemia (increased levels of bile pigment in the blood).

In pregnant women, an adequate supply of folic acid should be ensured.

The amounts of active substance detected in human milk are low and generally pose no danger to the infant. However, as a precaution, newborn infants and babies with glucose-6-phosphate dehydrogenase (a sugar metabolism enzyme) deficiency should not be breast-fed.

**Driving and using machines**

Very rarely, temporary short-sightedness and acute psychosis (mental/psychological illness) can occur during treatment with Cotrim E-ratiopharm® 480 mg/5 mL. In this case, you may no longer be able to respond quickly enough or appropriately enough to unexpected and sudden events. For this reason, please make sure that you know how you react to Cotrim E-ratiopharm® 480 mg/5 mL before driving or using machines. If in doubt, please ask your doctor.

**Important information about some of the ingredients of Cotrim E-ratiopharm® 480 mg/5 mL**

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product. 5 mL suspension (1 measuring spoon) contains 2.8 g sorbitol (a source of 0.7 g fructose), equivalent to 0.23 bread units. Sorbitol may have a mild laxative effect.

5 mL (1 measuring spoon) Cotrim E-ratiopharm® 480 mg/5 mL contains 0.53 to 0.56 mmol sodium. To be taken into consideration by patients on a controlled sodium diet.
Effects if misused for doping purposes
Due to the alcohol content, the use of Cotrim E-ratiopharm® 480 mg/5 mL may lead to positive results in doping tests.

3. How to take Cotrim E-ratiopharm® 480 mg/5 mL

Always take Cotrim E-ratiopharm® exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Unless otherwise prescribed by the doctor, the usual dose is:

Standard use

Adults and adolescents aged 13 years and older:
2 measuring spoonfuls of Cotrim E-ratiopharm® 480 mg/5 mL, twice daily.

Children aged 6 to 12 years:
1 measuring spoonful of Cotrim E-ratiopharm® 480 mg/5 mL, twice daily.

Children aged 6 months to 5 years:
½ measuring spoonful of Cotrim E-ratiopharm® 480 mg/5 mL, twice daily.

Infants aged 6 weeks to 5 months:
¼ measuring spoonful of Cotrim E-ratiopharm® 480 mg/5 mL, twice daily.

Note:
For higher and lower doses, medicines are available with a higher and lower active substance level.

Special dosing instructions

Long-term treatment in urinary tract infections to prevent a relapse

Adults and adolescents aged 13 years and older:
1½ - 2 measuring spoonfuls of Cotrim E-ratiopharm® 480 mg/5 mL, once daily.

Children aged 7 to 12 years:
¾ (½ + ¼) measuring spoonful of Cotrim E-ratiopharm® 480 mg/5 mL, once daily.

Children aged 1 to 6 years:
½ measuring spoonful of Cotrim E-ratiopharm® 480 mg/5 mL, once daily.

Infants aged 6 weeks and older:
¼ measuring spoonful of Cotrim E-ratiopharm® 480 mg/5 mL, once daily.

Pneumonia caused by Pneumocystis jiroveci
Cotrim E-ratiopharm® 480 mg/5 mL is administered at up to 5 times the standard dose (100 mg sulfamethoxazole/kg BW daily and 20 mg trimethoprim/kg BW daily). At the start of treatment, intravenous administration should be selected, at least for the first 48 hours.
Granuloma venereum (granuloma inguinale)
2 measuring spoonfuls of Cotrim E-ratiopharm® 480 mg/5 mL, twice daily, generally for 2 weeks.

Nocardiosis
2 measuring spoonfuls of Cotrim E-ratiopharm® 480 mg/5 mL, 3 times daily, generally for 8-10 weeks.

Note:
At the start of treatment, at least for the first 5-7 days, intravenous administration of the above daily dose with 2400 mg sulfamethoxazole and 480 mg trimethoprim should be selected.

Notes on dosage in impaired kidney function:
Your doctor will adjust the dose if your kidney function is impaired.

Method of administration
Cotrim E-ratiopharm® 480 mg/5 mL is taken with sufficient liquid after meals.
For dosing, please use the measuring spoon provided.

Duration of treatment
Your doctor will decide how long you should take this medicine. This will depend on the underlying disease and how it progresses. The following information serves as a guideline:

For bacterial infectious diseases, duration of treatment is guided by the progression of the disease. Normally, a treatment period of 5-8 days is sufficient. In the interests of a sustained response to treatment, Cotrim E-ratiopharm® 480 mg/5 mL should be taken for a further 2-3 days even after signs of disease have worn off.

For the treatment of pneumonia caused by Pneumocystis jiroveci, in the interests of a sustained response to treatment, a minimum treatment period of 14 days is indicated.

In urinary tract infections, long-term treatment to prevent a relapse is 3-12 months or even longer, if required.

Please talk to your doctor or pharmacist if you have the impression that the effect of Cotrim E-ratiopharm® 480 mg/5 mL is too strong or too weak.

If you take more Cotrim E-ratiopharm® 480 mg/5 mL than you should
If swallowed, significantly excessive amounts of this medicine will lead to vomiting, diarrhoea, headache, dizziness, as well as unusually little or no urine output or precipitation of tiny crystals in the urinary tract.
Please tell a doctor immediately if you suspect an overdose, so that he/she can decide what to do next and take appropriate measures, e.g. stomach pumping.

If you forget to take Cotrim E-ratiopharm® 480 mg/5 mL
If you happen to miss a dose of Cotrim E-ratiopharm® 480 mg/5 mL, keep taking Cotrim E-ratiopharm® 480 mg/5 mL as if nothing had happened. Please do not try and make up for a forgotten dose by using a larger amount of medicine at your next time. It is important that you take Cotrim E-ratiopharm® 480 mg/5 mL consistently and at regular intervals.
Effects when treatment with Cotrim E-ratiopharm® 480 mg/5 mL is stopped
Please do not stop taking Cotrim E-ratiopharm® 480 mg/5 mL too soon. The fight against the pathogens must be continued for a while, even after your symptoms have worn off. If not, the signs of disease may return. If you should notice any side effects, please talk to your treating doctor.

4. Possible side effects

Like all medicines, Cotrim E-ratiopharm® 480 mg/5 mL can cause side effects, although not everybody gets them.

The following frequencies are used for evaluating side effects:

<table>
<thead>
<tr>
<th>frequency</th>
<th>description</th>
</tr>
</thead>
<tbody>
<tr>
<td>very common</td>
<td>more than 1 in 10 patients treated</td>
</tr>
<tr>
<td>common</td>
<td>1 in 10 in 100 patients treated</td>
</tr>
<tr>
<td>uncommon</td>
<td>1 in 10 in 1,000 patients treated</td>
</tr>
<tr>
<td>rare</td>
<td>1 in 10 in 10,000 patients treated</td>
</tr>
<tr>
<td>very rare</td>
<td>less than 1 in 10,000 patients treated</td>
</tr>
<tr>
<td>not known</td>
<td>cannot be estimated from the available data</td>
</tr>
</tbody>
</table>

Common:
- Inflammation of the tongue, gums and mouth lining, unusual taste, gastrointestinal complaints with upper abdominal pain, loss of appetite, nausea, vomiting or diarrhoea.
- Hypersensitivity reactions with varying degrees of severity, such as skin rash (e.g. with hives, redness, blotches, lumps or small measles-like spots), itching, pinpoint bleeding of the skin and mucous membranes, skin disease caused by exposure to light and disease with formation of red skin nodules.

Uncommon:
- Ringing in the ears (tinnitus)
- Liver disease with bile congestion
- Decrease and increase in blood potassium levels together with a decrease in blood sodium levels (see 2. under "Take special care with Cotrim E-ratiopharm® 480 mg/5 mL"

Rare:
- Severe inflammation of the bowel lining (pseudomembranous colitis) – usually caused by Clostridium difficile (see 2. under "Take special care with Cotrim E-ratiopharm® 480 mg/5 mL"
- Serious hypersensitivity reactions of the skin, such as erythema exsudativum multiforme and exfoliative dermatitis (potentially life-threatening diseases, sometimes with skin peeling and possibly blistering of the skin and mucous membranes). These skin hypersensitivity reactions occur with varying degrees of severity and more frequently in patients with HIV infection.

Very rare:
- Severe and potentially life-threatening skin reactions (Stevens-Johnson syndrome and toxic epidermal necrolysis) (see section 2).
- These skin hypersensitivity reactions occur with varying degrees of severity and more frequently in patients with HIV infection.
- Increased occurrence of fungal infections caused by Candida albicans
- Headache, inflammation of the brain membrane (aseptic meningitis), dizziness, nerve inflammation, non-inflammatory nerve disease and abnormal sensations such as tingling or numbness in hands or legs, seizures, tremor
- Mental/psychological disorders (acute psychosis), hallucinations
- Movement coordination problems (ataxia), reduced ability to perform rapidly alternating movements (dysdiadochokinesia), muscle pain, joint pain
- Temporary short-sightedness, uveitis (inflammation of the eye’s choroid layer)
- Disintegration of liver tissue, a syndrome with atrophy (shrinkage) of the biliary tract and an increase in certain chemical blood test results (clinical/chemical laboratory parameters: transaminases, bilirubin), acute pancreatitis
- Overacidity of the blood, reduced blood sugar
- Precipitation of tiny crystals in the urinary tract, especially in malnourished patients, kidney inflammation, acute kidney failure, an increase in certain blood test results (clinical/chemical laboratory parameters: creatinine, urea)
- Hypersensitivity reactions of the lung (accumulation of inflammatory cells in lung tissue, certain forms of pneumonia and respiratory distress), occurring more frequently in patients with AIDS.
- Heart muscle inflammation, QT-time prolongation (ECG change), torsade de pointes (heart rate disorder)
- Abnormal blood counts (decrease in blood platelets, white blood cells, anaemia due to problems in blood formation, anaemia due to a lack of folic acid or vitamin B₁₂, etc., marked decrease in certain white blood cells, anaemia due to the breakdown of red blood cells) (see 2. under “Take special care with Cotrim E-ratiopharm® 480 mg/5 mL)
- Inflammation of smaller arteries and veins in the underlying skin layer (polyarteritis nodosa, Schoenlein-Henoch syndrome), systemic lupus erythematosus (a disorder of the body’s own immune system, with inflammation of many different organs), angioedema (skin swelling), petechial (pinpoint) skin bleeding, severe acute hypersensitivity reactions with anaphylactic shock (a sudden, severe pathological condition with a fall in blood pressure and risk of cardiac and respiratory arrest), which require appropriate emergency measures (see also section “Corrective measures”), drug fever, pseudosepsis (symptoms that mimic blood poisoning)

**General information**
Serious and life-threatening hypersensitivity reactions occur more frequently in elderly patients (over 60 years of age). Fatalities have been reported in association with side effects affecting the blood formation system and side effects of the skin.

**Corrective measures**
At the onset of headache, nausea, vomiting, apathy, unresponsiveness, states of confusion, dizziness, chills, fever, persistent diarrhoea and skin rash, treatment must be stopped immediately. In such cases, contact your nearest available doctor.

The following very rare side effects (see above for further details on these side effects) may be acutely life-threatening in some cases. A doctor must therefore be informed immediately if such an event should suddenly occur or unexpectedly get worse.

**Inflammation of the bowel lining (pseudomembranous enterocolitis)**
In this case, the doctor must consider stopping treatment with Cotrim E-ratiopharm® 480 mg/5 mL, depending on the indication (reason for using the medicine), and introduce appropriate treatment as necessary (e.g. intake of special antibiotics/chemotherapeutic agents with clinically proven effectiveness). Medicines that inhibit bowel motility (peristalsis) must not be taken.
Severe acute hypersensitivity reactions (e.g. anaphylactic shock)
In such cases, treatment with Cotrim E-ratiopharm® 480 mg/5 mL must be stopped immediately and appropriate emergency measures must be introduced (e.g. antihistamines, corticosteroids, sympathomimetics and, if required, artificial respiration).

Other possible side effects
Methylhydroxybenzoate (Ph.Eur.) and propylhydroxybenzoate (Ph.Eur.) may cause allergic reactions (possibly delayed).

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly to the Bundesinstitut für Arzneimittel und Medizinprodukte (= Federal Institute for Drugs and Medical Devices), Abt. Pharmakovigilanz (= Department of Pharmacovigilance), Kurt-Georg-Kiesinger Allee 3, D-53175 Bonn, website: http://www.bfarm.de. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Cotrim E-ratiopharm® 480 mg/5 mL
Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and label. The expiry date refers to the last day of that month.

Shelf life after opening: 6 months
This medicine does not require any special storage conditions.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Further information

What Cotrim E-ratiopharm® 480 mg/5 mL contains
The active substances are sulfamethoxazole and trimethoprim. 5 mL suspension contains 480 mg co-trimoxazole, equivalent to 400 mg sulfamethoxazole and 80 mg trimethoprim.

The other ingredients are:
Sorbitol solution 70% (non-crystallising) (Ph.Eur.), silica, sodium cyclamate, saccharin sodium, carmellose sodium, ethanol 96%, methylhydroxybenzoate (Ph.Eur.), propylhydroxybenzoate (Ph.Eur.), dimethicone, methyl cellulose, sorbic acid, banana flavouring (85509/H, Givaudan), vanisol flavouring (84262/31 Givaudan), purified water

What Cotrim E-ratiopharm® 480 mg/5 mL looks like and contents of the pack
White, thick viscous suspension.
Cotrim E-ratiopharm® 480 mg/5 mL is available in a pack with 100 mL solution.
Marketing Authorisation Holder
ratiopharm GmbH
Graf-Arco-Str. 3
D-89079 Ulm

Manufacturer
Merckle GmbH
Ludwig-Merckle-Str. 3
D-89143 Blaubeuren

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