

TRIMETHOPRIM 200MG TABLETS

(Trimethoprim)

PL 00289/0922

UKPAR

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TRIMETHOPRIM 200MG TABLETS

(Trimethoprim)

PL 00289/0922

LAY SUMMARY

On 26th May 2011, the MHRA granted TEVA UK Limited a Marketing Authorisation (licence) for the medicinal product Trimethoprim 200mg Tablets (PL 00289/0922). This medicine is only available on prescription from your doctor.

Trimethoprim belongs to a group of medicines called antibacterials. Trimethoprim is used for the prevention and treatment of infections, particularly in the urinary and respiratory tracts.

No new or unexpected safety concerns arose from this application and it was, therefore, judged that the benefits of taking Trimethoprim 200mg Tablets outweigh the risks; hence a Marketing Authorisation has been granted.

TRIMETHOPRIM 200MG TABLETS

(Trimethoprim)

PL 00289/0922

SCIENTIFIC DISCUSSION

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INTRODUCTION

Based on the review of the data on quality, safety and efficacy, the MHRA granted a Marketing Authorisation for the medicinal product Trimethoprim 200mg Tablets (PL 00289/0922) to TEVA UK Limited on the 26th May 2011. Trimethoprim is a Prescription only medicine used in the treatment of susceptible infections caused by trimethoprim -sensitive organisms including urinary tract and respiratory tract infections. It is also indicated for the prevention of recurrent urinary tract infections.

This application was submitted as an abridged application according to Article 10c of Directive 2001/83/EC, cross-referring to Trimethoprim 200mg Tablets (PL 00289/0197) which is also held by TEVA UK Limited, and was granted a Marketing Authorisation on 16th July 1991.

No new data were submitted nor were they necessary for this simple application, as the data are identical to that of the previously granted cross-reference product. As the cross-reference product was granted prior to the introduction of current legislation, no Public Assessment Report (PAR) has been generated.

A detailed pharmacovigilance system has been provided with this application and is satisfactory.

No environmental risk assessment has been undertaken, as this is not considered necessary. This is justified as it is not anticipated that the grant of this new marketing authorisation will result in an increase in the environmental exposure of the drug. The applicant's justification for absence of ERA is satisfactory.

PHARMACEUTICAL ASSESSMENT

LICENCE NO: PL 00289/0922

PROPRIETARY NAME: Trimethoprim 200mg Tablets

COMPANY NAME: TEVA UK Limited

E.C. ARTICLE: Article 10c of Directive 2001/83/EC

LEGAL STATUS: POM

1 INTRODUCTION

This is an informed consent application for Trimethoprim 200mg Tablets, submitted under Article 10c of Directive 2001/83/EC. The application cross-refers to Trimethoprim 200mg Tablets (PL 00289/0197), approved on 16th July 1991. The Marketing Authorisation Holder is TEVA UK Limited. The current application is considered valid.

2 MARKETING AUTHORISATION APPLICATION (MAA)

2.1 Name(s)

The proposed name of the product is Trimethoprim 200mg Tablets. The product has been named in line with current requirements.

2.2 Strength, pharmaceutical form, route of administration, container and pack sizes

The product contains the active ingredient trimethoprim.

The product is packed in Blister strips with pack sizes of 7, 10, 14, 21, 24, 28, 30, 56, 60, 70, 84, 90, 100, 110, 112, 120, 150, 160 and 168 tablets.

And

HDPE or polypropylene containers with caps or child resistant closures in packs of 50, 100 and 500 tablets.

Specifications and Certificates of Analysis for all packaging components used have been provided and are satisfactory. The packaging and pack sizes are the same as those for the reference product.

The proposed shelf life is 36 months with no special storage condition. The shelf-life and storage condition are identical to those for the reference product and are satisfactory.

2.3 Legal status

The product is a Prescription Only Medicine (POM).

2.4 Marketing authorisation holder/Contact Persons/Company

The proposed Marketing Authorisation Holder is TEVA UK Limited, Brampton Road, Hampden Park, Eastbourne, East Sussex, BN22 9AG

The Qualified Person (QP) responsible for pharmacovigilance is stated and a *Curriculum Vitae* (CV) is included.

2.5 Manufacturers

The proposed manufacturing sites are the same as those registered for the reference product and evidence of Good Manufacturing Practice compliance has been provided.

2.6 Qualitative and quantitative composition

The proposed composition is consistent with the details registered for the reference product.

2.7 Manufacturing process

The proposed manufacturing process is consistent with the details registered for the reference product and the maximum batch size is stated.

2.8 Finished product/shelf-life specifications

The proposed finished product and shelf-life specifications are in line with the details registered for the reference product.

2.9 Drug substance specification

The proposed drug substance specification conforms to the current European Pharmacopoeia monograph for trimethoprim, and is in-line with that for the reference product.

European Directorate for the Quality of Medicines (EDQM) Certificates of Suitability for trimethoprim has been provided. The active substance manufacturer is in line with that for the reference product.

2.10 TSE Compliance

No materials of human or animal origin have been used in the manufacture of this product. This is consistent with the reference product.

2.11 Bioequivalence

No bioequivalence data are required to support this informed consent application, as the proposed product is manufactured to the same formula utilising the same process as the reference product Trimethoprim 200mg Tablets (PL 00289/0197).

3 EXPERT REPORT

The applicant has included detailed expert reports of the application. Signed declarations and copies of the experts' CVs are enclosed for the quality, non-clinical and clinical experts. All are considered to have sufficient experience for their responsibilities.

4. PRODUCT NAME & APPEARANCE

See 2.1 for details of the proposed product name. The appearance of the product is identical to that of the reference product.

5. SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

The proposed SmPC is consistent with the details registered for the reference product.

6. PATIENT INFORMATION LEAFLET (PIL)/LABELLING

The applicant has submitted results of PIL user testing. The results indicate that the PIL is well-structured and organised, easy to understand and written in a comprehensive manner. The test shows that the patients/users are able to act upon the information that it contains.

The proposed artwork complies with the relevant statutory requirements. In line with current legislation the applicant has also included the name of the product in Braille on the outer packaging and has included sufficient space for a standard UK pharmacy dispensing label.

7. CONCLUSIONS

The data submitted with the application is acceptable. The grant of a Marketing Authorisation is recommended.

PRECLINICAL ASSESSMENT

No new preclinical data have been supplied with this application and none are required for an application of this type.

CLINICAL ASSESSMENT

No new clinical data have been supplied with this application and none are required for an application of this type.

OVERALL CONCLUSION AND BENEFIT RISK ASSESSMENT

QUALITY

The data for this application are consistent with those previously assessed for the reference product and, as such, have been judged to be satisfactory.

PRECLINICAL

No new preclinical data were submitted and none are required for an application of this type.

EFFICACY/SEFETY

This application is identical to the previously granted application for Trimethoprim 200mg Tablets (PL 00289/0197), granted to TEVA UK Limited on the 16th July 1991.

Pharmaceutical, preclinical and clinical expert statements have been provided, together with CVs showing the experts are appropriately qualified. The experts confirm that the product is identical in composition, manufacture and pharmaceutical characteristics to the respective reference product and that there are no toxicological or clinical issues.

No new or unexpected safety concerns arise from this application.

The SmPC, PIL and labelling are satisfactory and consistent with those for the reference product.

RISK BENEFIT ASSESSMENT

The quality of the product is acceptable and no new preclinical or clinical safety concerns have been identified. The applicant's product is identical to the reference product. Extensive clinical experience with trimethoprim is considered to have demonstrated the therapeutic values of the compounds. The risk benefit is, therefore, considered to be positive.

TRIMETHOPRIM 200MG TABLETS**(Trimethoprim)****PL 00289/0922****STEPS TAKEN FOR ASSESSMENT**

1	The MHRA received the marketing authorisation application on 20 th October 2005
2	Following standard checks and communication with the applicant the MHRA considered the application valid on 7 th November 2005
3	Following assessment of the application the MHRA requested further information on 18 th January 2006, 10 th October 2006 and 3 rd November 2010
4	The applicant responded to the MHRA's request, providing further information on 10 th October 2006, 5 th March 2010, and 24 th February 2011
5	The application was determined on 26 th May 2011

SUMMARY OF PRODUCT CHARACTERISTICS**1 NAME OF THE MEDICINAL PRODUCT**

Trimethoprim 200 mg Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 200 mg of trimethoprim. For excipients, see 6.1

3 PHARMACEUTICAL FORM

Tablet

White, normal biconvex tablets, engraved 3H7 with a breakline on reverse.

4 CLINICAL PARTICULARS**4.1 Therapeutic indications**

Trimethoprim is indicated for the treatment of susceptible infections caused by trimethoprim - sensitive organisms including urinary tract and respiratory tract infections.

Trimethoprim is also indicated for the prevention of recurrent urinary tract infections.

4.2 Posology and method of administration

For oral administration

*Acute infections:**Adults and children over 12 years of age:* 200 mg twice daily*Children 6 years to 12 years:* 100 mg twice daily*Children 6 months to 5 years:* 50 mg twice daily

The approximate dosage in children is 8 mg trimethoprim per kg body weight per day.

Elderly: Depending on kidney function, see special dosage schedule.

Treatment should continue for at least one week but not last longer than two weeks. The first dose can be doubled.

*Long-term treatment and prophylactic therapy:**Adults and children over 12 years:* 100 mg at night*Children 6 years to 12 years:* 50 mg at night

The approximate dosage in children is 2 mg trimethoprim per kg body weight per day.

Elderly: Depending on kidney function, see special dosage schedule.**Dosage advised where there is reduced kidney function:**

Creatinine clearance ml/sec	Plasma creatinine micromol/l	Dosage advised
Over 0.45	Men <250 Women <175	Normal
0.25-0.45	Men 250-600 Women 175-400	Normal for 3 days then half dose.
Under 0.25	Men > 600 Women > 400	Half the normal dose.

Trimethoprim is removed by dialysis. It should not, however, be administered to dialysis patients unless plasma concentrations can be estimated regularly.

4.3 Contraindications

Trimethoprim is contra-indicated in pregnancy, trimethoprim hypersensitivity, blood dyscrasias, severe hepatic insufficiency and also in severe renal insufficiency, unless blood trimethoprim concentrations can be monitored regularly.

4.4 Special warnings and precautions for use

In patients with marked impairment of renal function, care should be taken to avoid accumulation and resulting adverse haematological effects.

Caution should be exercised in the administration of trimethoprim to patients with actual or potential folate deficiency (e.g. the elderly). Administration of a folate supplement should be considered. Although an effect on folic acid metabolism is possible, interference with haematopoiesis rarely occurs at the recommended dose. If any such change occurs, folinic acid should reverse the effect. Elderly people may be more susceptible and a lower dose may be advisable.

Regular haematological tests should be undertaken in patients receiving long term treatment and those predisposed to folate deficiency. Particular care should be exercised in the haematological monitoring of children on long term therapy. The usual caution in prescribing any drug for women of child bearing age should be exercised with trimethoprim.

Trimethoprim should be used under careful medical supervision in neonates.

Trimethoprim could cause contraceptive failure in patients who are taking oral contraceptives and have diarrhoea.

4.5 Interaction with other medicinal products and other forms of interaction

Anti-arrhythmics: Trimethoprim increases plasma concentrations of procainamide.

Antimalarials: Increased antifolate effect when trimethoprim is given with pyrimethamine.

Cytotoxics: Increased risk of haematological toxicity when trimethoprim is given with azathioprine or mercaptopurine. Trimethoprim increases the antifolate effect of methotrexate therefore use should be avoided.

Taking oral contraceptives and having diarrhoea, could cause contraceptive failure.

Rifampicin may increase the elimination and shorten the elimination half-life of trimethoprim.

With bone marrow depressants, trimethoprim may increase the potential for bone marrow aplasia.

Digoxin and phenytoin: Trimethoprim may increase the elimination half-life of phenytoin and digoxin therefore patients should be carefully controlled.

Ciclosporin may increase the nephrotoxicity of trimethoprim.

Trimethoprim may potentiate the anticoagulant effect of warfarin.

4.6 Pregnancy and lactation

Trimethoprim is contra-indicated in pregnant women. Trimethoprim is excreted in breast milk but is not contra-indicated for short term use in lactating mothers.

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

Nausea, vomiting, gastrointestinal disturbances and headache have been reported. These side effects are rare.

Skin rash, pruritis and urticaria have been reported occasionally. More severe skin sensitivity reactions such as erythema multiforme, Stevens-Johnson Syndrome and epidermal necrolysis have been reported rarely.

Photosensitivity, anaphylactic reactions, anaphylactoid reactions and angioedema have been reported rarely.

Isolated cases of megaloblastic anaemia during prolonged therapy with trimethoprim, with higher doses than those recommended, have been reported. These effects are reversible with discontinuation of therapy and administration of calcium folinate.

Aseptic meningitis has been reported.

Trimethoprim may affect haematopoiesis.

4.9 Overdose

Symptomatic treatment, gastric lavage and forced diuresis can be used. Depression of haematopoiesis by trimethoprim can be counteracted by intramuscular administration of calcium folinate.

5 PHARMACOLOGICAL PROPERTIES**5.1 Pharmacodynamic properties**

ATC code: J01EA01 Sulfonamides And Trimethoprim (*Trimethoprim and derivatives*)
Trimethoprim inhibits dihydrofolate reductase and thus prevents the synthesis of tetrahydrofolic acid from dihydrofolic acid. It therefore affects the nucleoprotein metabolism of micro-organisms.

5.2 Pharmacokinetic properties

Trimethoprim is readily absorbed from the gastro-intestinal tract and peak concentrations in the circulation occur about 3 hours after a dose is taken. About 45% is bound to plasma proteins. Tissue concentrations are reported to be higher than serum concentrations with particularly high concentrations in the kidneys and lungs. Concentrations in the CSF are about half that of those in blood. The half life is about 10-16 hours. 40-50 % of the dose is excreted unchanged in the urine within 24 hours.

5.3 Preclinical safety data

Preclinical information has not been included because the safety profile of trimethoprim has not been established after many years of clinical use. Please refer to section 4.

6 PHARMACEUTICAL PARTICULARS**6.1 List of excipients**

The tablet contains:
Lactose Monohydrate
Maize Starch
Microcrystalline Cellulose
Sodium Starch Glycolate (Type A)
Povidone
Colloidal Anhydrous Silica
Magnesium Stearate
Stearic Acid

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

36 months.

6.4 Special precautions for storage

Not applicable.

6.5 Nature and contents of container

Blister strips in packs of 7, 10, 14, 21, 24, 28, 30, 56, 60, 70, 84, 90, 100, 110, 112, 120, 150, 160 and 168 tablets.
HDPE or polypropylene containers with caps or child resistant closures in packs of 50, 100 and 500 tablets.

6.6 Special precautions for disposal

Not applicable.

7 MARKETING AUTHORISATION HOLDER

TEVA UK Limited
Brampton Road, Hampden Park,
Eastbourne, East Sussex, BN22 9AG

8 MARKETING AUTHORISATION NUMBER(S)

PL 00289/0922

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

26/05/2011

10 DATE OF REVISION OF THE TEXT
26/05/2011

PATIENT INFORMATION LEAFLET

TRIMETHOPRIM 200 mg TABLETS

PACKAGE LEAFLET: INFORMATION FOR THE USER

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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

IN THIS LEAFLET:

1. What Trimethoprim is and what it is used for
2. Before you take Trimethoprim
3. How to take Trimethoprim
4. Possible side effects
5. How to store Trimethoprim
6. Further information

1 WHAT TRIMETHOPRIM IS AND WHAT IT IS USED FOR

- Trimethoprim belongs to a group of medicines called antibacterials.
- Trimethoprim is used for the prevention and treatment of infections, particularly in the urinary and respiratory tracts.

2 BEFORE YOU TAKE TRIMETHOPRIM

Do NOT take Trimethoprim:

- If you are allergic (hypersensitive) to trimethoprim or any of the other ingredients of this medicine
- If you are pregnant or breast-feeding
- If you have any blood disorders
- If you suffer from severe liver problems
- If you suffer from severe kidney problems, unless your doctor is checking the levels of trimethoprim in your blood.

Take special care with Trimethoprim

Tell your doctor before you start to take this medicine if you:

- Have kidney problems
- Have folate-deficiency anaemia (a decrease in red blood cells due to a poor diet, which can cause tiredness, headache, a sore mouth and tongue and pale skin).

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

The effect of Trimethoprim may be increased or decreased by other medicines and vice versa.

These medicines include:

- Azathioprine (used following organ transplant and for arthritis)
- Ciclosporin (used to prevent organ rejection after transplant surgery)
- Digoxin or procainamide (used to treat heart problems)
- Mercaptopurine or methotrexate (used as bone marrow depressants)
- Phenytoin (used to treat epilepsy)
- Pyrimethamine (used to treat malaria)
- Rifampicin (used to treat infections)
- Warfarin (used to prevent blood clots).

If you are taking oral contraceptives ("the pill") and have diarrhoea, this could cause contraceptive failure. It is recommended that you use other forms of contraception such as the diaphragm or condom while you are taking trimethoprim, and for 7 days after the course has been completed.

Pregnancy and breast-feeding

Do not take trimethoprim if you are pregnant or breast-feeding.

Ask your doctor or pharmacist for advice before taking any medicine.

Important information about some of the ingredients of Trimethoprim

Patients who are intolerant to lactose should note that Trimethoprim tablets contain a small amount of lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3 HOW TO TAKE TRIMETHOPRIM

Always take Trimethoprim exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

The tablets should be swallowed with a drink of water.

The usual dose is:

Severe or sudden infections:

Adults and children over 12 years of age:

200 mg twice a day.

Children aged 6 to 12:

100 mg twice a day.

Children 6 months to 5 years:

50 mg twice a day.

Elderly:

The adult dose may need to be reduced depending on how well your kidneys function. Your doctor will advise you.

The treatment should continue for at least one week but no longer than two weeks.

For long term treatment and for the prevention of infections:

Adults and children over 12 years of age:

100 mg at night.

Children aged 6 to 12 years of age:

50 mg at night.

Trimethoprim suspension is available for use in children.

Elderly:

The adult dose may need to be reduced depending on how well your kidneys function. Your doctor will advise you.

Renal impairment:

It may be necessary to reduce the dosage if you are suffering from kidney problems. Your doctor will advise you.

Dialysis patients:

Dialysis removes trimethoprim. Blood tests will be carried out before and after dialysis.

You should continue to take these tablets for as long as your doctor tells you to. Take the full course. Even if you start to feel better the original infection may still be present and may recur if treatment is stopped.

You may need to have blood tests if you take Trimethoprim for a long time or if your doctor thinks you are at special risk.

If you take more Trimethoprim than you should

If you (or someone else) swallow a lot of the tablets all together, or if you think a child has accidentally swallowed any of the tablets, contact your nearest hospital casualty department or your doctor immediately. Please take this leaflet, any remaining tablets and the container with you to the hospital or doctor so that they know which tablets were consumed.

If you forget to take Trimethoprim

If you forget to take a tablet, take one as soon as you remember, unless it is nearly time to take the next one. Do not take a double dose to make up for a forgotten tablet. Take the remaining doses at the correct time.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4 POSSIBLE SIDE EFFECTS

Like all medicines, Trimethoprim can cause side effects, although not everybody gets them.

If the following happens, stop taking Trimethoprim and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Difficulty in breathing and swelling of the lips, face and neck.
- Severe skin reactions, including blistering/bleeding of the lips, eyes, nose, mouth and genitals, or the skin peeling off.

These are very serious but rare side effects. You may need urgent medical attention or hospitalisation.

Other side effects may include:

- Stomach upset, abdominal pain
- Headache

- Feeling sick or being sick
- Changes in how your body makes new blood cells
- Skin redness, skin rashes and itching
- Sensitivity to light
- Anaemia (characterised by tiredness, headache, a sore mouth and tongue)
- Sudden severe headache or stiffness of the neck accompanied by a high temperature.

If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5 HOW TO STORE TRIMETHOPRIM

Keep out of the reach and sight of children. Do not take Trimethoprim after the expiry date that is stated on the outer packaging.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6 FURTHER INFORMATION**What Trimethoprim contains:**

- Each tablet contains 200 mg of the active substance, trimethoprim.
- The other ingredients are lactose monohydrate, maize starch, microcrystalline cellulose, sodium starch glycolate (Type A), povidone, colloidal anhydrous silica, magnesium stearate and stearic acid.

What Trimethoprim looks like and contents of the pack:

- The name of your medicine is Trimethoprim 200 mg Tablets
- Trimethoprim 200 mg Tablets are white, normal biconvex tablets, engraved "3H7" with a breakline on the reverse
- Trimethoprim 200 mg tablets are available in pack sizes of 7, 10, 14, 21, 24, 28, 30, 50, 56, 60, 70, 84, 90, 100, 110, 112, 120, 150, 160, 168 and 500 tablets.
- Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation holder and company responsible for manufacture: TEVA UK Limited, Eastbourne, BN22 9AG.

This leaflet was last revised: February 2011.

PL 00289/0922



TEVA UK LIMITED

12345-T

LABELLING



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