13 May 2022

BACTRIMEL: END OF COMMERCIALISATION OF BACTRIM 80 MG/5 ML + 400 MG/5 ML ORAL SUSPENSION (AIC 021978061) AND NEW AVAILABILITY OF BACTRIMEL 40 MG + 8 MG / ML ORAL SUSPENSION (AIC 048950012)

Dear Healthcare Professional,

In agreement with the Italian Medicines Agency (AIFA), Eumedica Pharmaceuticals GmbH wishes to inform you that the current formulation of BACTRIM 80 MG / 5 ML + 400 MG / 5 ML oral suspension (AIC 021978061) will be replaced by the new formulation BACTRIMEL 40 MG + 8 MG / ML oral suspension (AIC 048950012)
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Summary Information

- The current formulation of BACTRIM 80 MG/5 ML + 400 MG/5 ML ORAL SUSPENSION can no longer be produced due to a long-term unavailability of one of its components.
- A new formulation is now available: BACTRIMEL 40 MG/ML + 8 MG/ML ORAL SUSPENSION
- The active substance strength of the new formulation is halvened when compared to the previous formulation. A particular attention should be drawn as to the new product concentration so that the patient is still receiving the appropriate regimen.
- For a limited time, it is anticipated that there will be an overlap in availability of the new formulation with the old one. In the interest of good practice and to avoid medication error, this situation requires attention.
- The packs of the two formulations on the market will be easily distinguished in that the packs of BACTRIM will continue to show Roche S.p.A as the marketing authorization holder, while the packs of BACTRIMEL with the new formulation will be placed on the market under Eumedica Pharmaceuticals GmbH as the marketing authorization holder.

Further information

The current formulation of BACTRIM 80 MG/5 ML + 400 MG/5 ML ORAL SUSPENSION can no longer be produced due to a long-term unavailability of one of its components.
The current stock will last until end-June 2022. In order to guarantee the continuity of patient care, the formulation BACTRIM 80 MG/5 ML + 400 MG/5ML ORAL SUSPENSION currently on the market will permanently be replaced by a new formulation: BACTRIMEL 40 MG/ML + 8 MG/ML ORAL SUSPENSION.
Although newly available in Italy, this oral suspension has already been marketed in other European countries for several years.
This product is presented in a brown glass bottle containing 100 mL of oral suspension, with a measuring spoon graduated at 1.25 mL, 2.5 mL and 5 mL. The capacity of the bottle is identical to that of the previous formulation. The measuring spoon is transparent instead of yellowish and shows graduation to allow accurate dosing.

It is important to stress that this new formulation differentiates from the former one in several aspects:

- Do not store the new formulation BACTRIMEL 40 MG/ML + 8 MG/ML ORAL SUSPENSION above 25°C. After first opening. Use within 8 weeks of first opening.
- The strength of active substance (trimethoprim/sulfamethoxazole) in the new formulation BACTRIMEL 40 MG/ML + 8 MG/ML SOSPENSIONE ORALE is halvened when compared to the current formulation BACTRIM 80 MG/5 ML + 400 MG/5 ML SOSPENSIONE ORALE. This strength increases the accuracy in

the dosing while decreasing possible waste of unused medicine. Yet, in order to avoid any underdosing, this should be taken into account in the dosing recommendations and clearly specified to patients.

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Current formulation	New formulation
5 mL of oral suspension contain 400 mg di sulfametoxazolo e 80 mg di trimetoprim	5 mL of oral suspension contain 200 mg di sulfametoxazolo e 40 mg di trimetoprim

For the full summary of product characteristics and product information leaflet, please see: https://farmaci.agenziafarmaco.gov.it/bancadatifarmaci/

BACTRIMEL ORAL SUSPENSION is indicated in adults, adolescents, children and infants from the age of 6 weeks for the following indications: upper urinary tract infections, complicated lower urinary tract infections, prostatitis, serious infections originating from the urinary tract, acute exacerbation of chronic bronchitis, shigellosis, typhoid and paratyphoid fever, treatment of infections caused by Pneumocystis jirovecii; prophylaxis of infections caused by Pneumocystis jirovecii, particularly in immunocompromised patients.

It is anticipated that there will be an overlap in availability of the new formulation with the current one after which the current formulation will no longer be available.
In this regard, it is to be noted that the packs of these two formulations on the market will be easily distinguished in that the packs of the current formulation will continue to show Roche S.p.A as the marketing authorization holder, while the packs with the new formulation will be placed on the market under Eumedica Pharmaceuticals GmbH as the marketing authorization holder.

Recommendation to report

The reporting of suspected adverse reactions that occur after the authorization of the medicine is important, as it allows continuous monitoring of the benefit / risk ratio of the medicine. Healthcare professionals are asked to report any suspected adverse reactions via the national reporting system: Italian Medicines Agency, website:
https://www.aifa.gov.it/content/segnalazioni-reazioni-avverse.

AIFA takes this opportunity to remind all Healthcare Professionals of the importance of reporting suspected adverse drug reactions, as an indispensable tool to confirm a favourable benefit / risk ratio in real conditions of use.
Reports of Suspected Adverse Reaction from drugs must be sent to the Head of Pharmacovigilance of the Facility to which the Operator belongs.
This Information Note is also published on the AIFA website (http://www.aifa.gov.it) whose regular consultation is recommended for the best professional and service information to the citizen.