

- Lavez-vous les mains.
- N'ouvrez pas l'emballage si l'ovule vous semble mou. Passez-le sous l'eau froide ou mettez-le au réfrigérateur pendant quelques minutes afin de le durcir avant de retirer l'emballage.
- Enlevez un ovule de l'emballage et maintenez-le du bout des doigts.
- Retirez de l'ovule tout morceau de plastique ou d'aluminium collé.
- Asseyez-vous ou allongez-vous avec vos genoux pliés et les jambes écartées.
- Insérez doucement l'ovule dans le vagin en vous aidant de l'extrémité du doigt pour terminer l'insertion.
- Lavez-vous les mains à nouveau.



Conseils pratiques :

- Le traitement s'accompagnera de conseils d'hygiène (port de sous-vêtements en coton, éviter les douches vaginales, le port de tampon interne pendant le traitement...) et, dans la mesure du possible, de la suppression des facteurs favorisants.
- Ne pas interrompre le traitement pendant les règles.

Si vous avez pris plus de GYNANFORT® que vous n'auriez dû

En cas de vomissements, difficulté à coordonner les mouvements, désorientation, consultez votre médecin.

Si vous oubliez de prendre GYNANFORT®

Sans objet.

Si vous arrêtez de prendre GYNANFORT®

Sans objet.

Si vous avez d'autres questions sur l'utilisation de ce médicament, demandez plus d'informations à votre médecin ou à votre pharmacien.

4. Effets secondaires possibles

Comme tous les médicaments, GYNANFORT® peut provoquer des effets indésirables, mais ils ne surviennent pas systématiquement chez tout le monde.

- Engourdissement, contractures musculaires et convulsions ;
- Troubles gastro-intestinaux, nausées et/ou vomissements, diarrhées, anorexie (manque d'appétit), goût métallique dans la bouche, gonflements abdominaux ;
- Troubles neurologiques : maux de tête, vertiges, dépression ;
- Troubles dermatologiques : urticaire, démangeaisons, en cas d'irritation, le traitement doit être interrompu ;
- Exceptionnellement : crampes, fatigue, urines foncées.

Si vous ressentez un des effets mentionnés comme grave ou si vous présentez des effets indésirables non mentionnés dans cette notice, veuillez en informer votre médecin ou votre pharmacien.

5. Comment conserver GYNANFORT®

Conserver en dessous de 30°C, à l'abri de la lumière.

Tenir hors de la portée et de la vue des enfants.

Ne pas utiliser après la date de péremption indiquée sur l'emballage.

Les médicaments ne doivent pas être jetés au tout à l'égout ou avec les ordures ménagères. Demandez à votre pharmacien ce qu'il faut faire des médicaments inutilisés. Ces mesures permettront de protéger l'environnement.

6. Contenu de l'emballage et autres informations

Quelle est la composition de GYNANFORT®

Composition: Chaque ovule contient

Métronidazole	500 mg
Sulfate de Néomycine	65 000 U.I.
Nystatine	100 000 U.I.
Excipients	q.s.p.

Excipients à effet notoire: polyéthylène glycol

Autres excipients: Méthylparabène, propylparabène, hydroxytoluène butylé.

Aspect de GYNANFORT® et contenu de l'emballage

Ovules pour usage vaginal.

Boîte de 10 ovules.

Cette notice a été mise à jour en 10/2021.

Si vous avez des questions sur ce produit ou si vous souhaitez signaler un effet indésirable contactez-nous par téléphone : + 225 21 25 52 38.

Titulaire & exploitant AMM: **IMEX PHARMA**

Rose Belle Building, Unit 3, Rose Belle Business Park, Mauritius.

Fabriqué par: **BLISS GVS PHARMA LTD.**

Dewan Udyog Nagar, Aliyali, Palghar, Maharashtra - 401 404, INDIA.

PATIENT INFORMATION LEAFLET: INFORMATION FOR THE USER
GYNANFORT®

Metronidazole, Neomycin Sulphate & Nystatin Pessaries

Please read this leaflet completely before taking this medicine as it contains important information:

- Keep this leaflet, as you may need to read it again.
- Ask your doctor or pharmacist if you have further questions.
- This medicine was prescribed for you only. Do not give it to others. It may harm them, even if their symptoms are identical to yours.
- If you have any side effects, including some that are not listed in this leaflet, inform your doctor or pharmacist.

What is in this leaflet:

1. What is GYNANFORT® and when to use it
2. What you need to know before taking GYNANFORT®
3. How to take GYNANFORT®
4. Possible side effects
5. How to store GYNANFORT®
6. Contents of the pack and other information

1. What is GYNANFORT® and when to use it

GYNANFORT® is indicated for the treatment of local vaginal fungal and bacterial infections treating local (gram negative infections including Pseudomonas) in adults.

2. What you need to know before taking GYNANFORT®

Do not take GYNANFORT®

- If you are allergic to metronidazole, neomycin sulphate, nystatin or any of the other ingredients in GYNANFORT® (se section 6);
- If you have a history of allergy or severe reaction to aminoglycosides;

Precautions with GYNANFORT®

- Aminoglycosides should be used with caution in patients with muscle disorders such as myasthenia or parkinsonism as these substances can increase the muscular weakness due to their effect similar to curare on the neuromuscular junction;
- In case of irritation the treatment must be terminated.

Concomitant use of GYNANFORT® with other drugs

- Caution should be used when concomitantly or occasionally using other aminoglycosides as these can increase nephrotoxicity and/or ototoxicity and reinforce the neuromuscular antagonist effects of the neomycin;
- Spermicides: any local treatment can inactivate a local spermicide contraception;
- Alcohol: antabuse effect (heat, redness, vomiting, tachycardia). Avoid alcoholic beverages or medicines containing alcohol;
- Disulfiram: concomitant use of disulfiram can cause outburst of delirium or confused state;
- Oral anticoagulants (warfarin): the effect of oral anticoagulants as well as the risk of haemorrhaging is increased due to the decreased hepatic catabolism. The dosage of the oral anticoagulants should be adapted during the treatment with metronidazole and 8 days after its termination;
- 5-fluoro-uracile: increased toxicity of the 5-FU due to the decrease of its clearance.

Pregnancy and breast-feeding

Pregnancy:

Given the presence of neomycin, which is an aminoglycoside, there is a fetotoxic risk and the possibility of a systemic transition. Therefore this medicine is not recommended when pregnant, unless your doctor deems that the benefits outweigh the risks associated to the treatment.

Breast-feeding:

As there is no data on the passage of this medicine in human milk, it should be avoided when breast-feeding.

Driving and using machines

Caution should be taken when driving or using machines considering the risk of dizziness associated with the use of this medicine.

3. How to take GYNANFORT®

Always take the dose recommended by your doctor. In case of doubt, consult your doctor or pharmacist.

Dosage and administration

1 -2 pessaries daily for 10 days or follow the doctor's prescription.

Do not use GYNANFORT® in infants.

A treatment with GYNANFORT® should not be prescribed for more than 10 days. It should not be repeated more than 2 to 3 times a year.

- Wash your hands.

- Do not open pessary if it seems soft, hold the foil wrapper under cold water or place it in refrigerator for few minutes to harden it before removing the wrapper.
- Remove one pessary from the strip and hold it in fingertips.
- Remove any foil or plastic wrapping stuck to the suppository.
- Sit or lie down with your knees bent and legs apart.
- Gently insert the pessary into the vagina as far as comfortably possible using your fingers.
- Wash your hands again.



Practical advice:

- The treatment will be accompanied by advice on hygiene (wearing cotton underwear, avoiding vaginal washes, avoiding the use of tampons during the treatment...) and as much as possible avoiding contributory factors.
- Do not interrupt treatment during period.

If you have taken more GYNANFORT® than prescribed

In case of vomiting, difficulty to coordinate movement or disorientation, consult your doctor.

If you have forgotten to take GYNANFORT®

Not-applicable.

If you stop taking GYNANFORT®

Not-applicable.

If you have any other questions pertaining to the use of this medicine or wish to stop the treatment, please inform your doctor or pharmacist.

4. Possible side effects

As with all medicines, GYNANFORT® can cause side effects, although not everybody may experience them.

- Numbness, muscle spasms and convulsions;
- Gastrointestinal disorders, nausea and / or vomiting, diarrhoea, anorexia (lack of appetite),
- metallic taste in the mouth, abdominal swelling;
- Neurological disorders: headaches, dizziness, depression;
- Skin disorders: hives, itching, in case of irritation treatment should be discontinued;
- Exceptionally: cramps, fatigue, dark urine.

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

5. How to store GYNANFORT®

Store below 30°C, protect from light.

Keep out of reach and sight of children.

Do not use after the expiry date.

Do not dispose via waste water or with household wastes. Ask your pharmacist how to dispose of unused drugs. These measures allow protecting the environment

6. Pack content and other information

What is the composition of GYNANFORT®

Composition: Each pessary contains	
Metronidazole	500mg
Neomycin Sulphate	65,000 I.U.
Nystatin	100,000 I.U.
Excipient	q.s.

Excipients with known effect: polyethylene glycol

Other excipients: Methylparaben, propylparaben, butylated hydroxytoluene.

Appearance of GYNANFORT® and pack content

For vaginal use only

Box of 10 pessaries.

This leaflet was last updated in 10/2021.

If you have any questions about this product or would like to report an adverse reaction contact us by phone : + 225 27 21 25 52 38

MA Holder & operator: **IMEX PHARMA**

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