

## PATIENT INFORMATION LEAFLET

### **POLGYL 0.5% Solution for I.V. Perfusion**

**Administered by injection into the vein.**

Sterile

- **Active ingredient:** Each 100-ml PVC/PP bag contains 500 mg metronidazole.
- **Excipients:** Disodium phosphate, Sodium chloride, Citric acid monohydrate, Water for Injection.

**Please read this PATIENT INFORMATION LEAFLET carefully before starting to use the drug; because important information is included here.**

- *Keep this PATIENT INFORMATION LEAFLET. You may need to re-read it later.*
- *In case you have additional questions, please consult your doctor or pharmacist.*
- *This drug is prescribed personally for you, do not give to others.*
- *During the use of this drug, please tell your doctor that you are using this drug when you visit your doctor or a hospital.*
- *Please follow these instructions strictly. Do not use dosages **higher or lower** than the dosage recommended to you.*

#### **In this leaflet:**

- 1. What is POLGYL and what it is used for**
- 2. Before you are given POLGYL**
- 3. How you will be given POLGYL**
- 4. Possible side effects**
- 5. How to store POLGYL**

**headlines are included.**

#### **1. What is POLGYL and what it is used for?**

POLGYL solution for perfusion is used to treat intestinal amebiasis (an infection caused by amoeba), liver amebiasis, non-specific vaginitis (vaginal infection), anaerobic infections and genital infections caused by trichomonas.

POLGYL is available in 100-ml PVC and PP bags.

#### **2. Before you are given POLGYL**

##### **DO NOT USE POLGYL under the following conditions:**

This drug must not be used in patients who are hypersensitive against imidazole derivatives or excipients existing in the formulation.

##### **USE POLGYL CAREFULLY under following conditions:**

- If you have/have had problems in your liver

- If you are under dialysis therapy because of renal failure
- If you have any disease regarding your nervous system
- Alcoholic drinks must be avoided during the treatment; after the completion of your treatment, you must avoid alcoholic drinks for at least 48 hours
- Metronidazole must be used carefully in cases of any genetic disorders related to blood in the medical history
- In cases where POLGYL must be used for a long term, this must be decided upon after careful evaluation.

### **Use of POLGYL with foods and drinks**

Since POLGYL is administered intravenously, it can be taken with empty or full stomach.

### **Pregnancy**

*Consult your doctor or pharmacist before using this drug.*

POLGYL must not be used within the first 3 months of pregnancy. After the first 3 months of pregnancy, it should be used only if it is absolutely necessary.

*In case you realize that you are pregnant during the treatment, immediately consult your doctor or pharmacist.*

### **Lactation**

*Consult your doctor or pharmacist before using this drug.*

Since Metronidazole is excreted to the human milk, it must not be used during lactating period.

### **Driving and using machines**

During the POLGYL therapy, adverse effects that might affect your driving or using machines can be observed (for example, confusion, vertigo, hallucinations, impaired vision, etc.). Do not drive or use machines if you experience any of these adverse effects.

### **Important information about some excipients contained in POLGYL**

This medicinal product contains 13 mmol sodium per each 100 ml. This should be considered for patients on a controlled sodium diet.

### **Taking with other medicines**

Metronidazole can cause confusion and similar psychological reactions when used together with disulphiram therapy.

For patients who will have warfarin treatment, dosage should be adjusted carefully.

Moreover, if you are being treated with the following drugs, please inform your doctor: Lithium, vecuronium, phenobarbital or phenytoin, 5-fluorourasil, busulfan, cyclosporine.

*If you are currently using any prescribed or unprescribed drug, or if you have used them recently, please inform your doctor or pharmacist.*

### **3. How POLGYL will be given?**

#### **Instructions for proper use and dosage/administration intervals:**

POLGYL is a drug which is used for specific conditions. Your doctor will decide the amount of this drug that you need and dose intervals.

#### **Route and method of administration:**

It is administered intravenously by injection.

#### **Different age groups:**

##### **Children:**

POLGYL is used in children aged minimum 8 weeks.

##### **Elderly:**

Use of POLGYL in the elderly requires special care particularly at high doses.

#### **Special conditions of use**

##### **Renal/hepatic impairment:**

Since this drug is excreted through the kidneys, treatment of patients with renal failure receiving dialysis therapy requires care.

Your doctor may consider the lower doses or shorter treatment periods if you have liver failure.

Your doctor will decide the amount of the drug that you need and time intervals and will administer the drug to you.

*If you have an impression that the effect of POLGYL is too strong or too weak, consult your doctor or pharmacist.*

##### **If you use more POLGYL than you should:**

*Consult a doctor or a pharmacist if you used more POLGYL than you should.*

##### **If you forget to take POLGYL:**

*Do not take double dosage to balance the skipped dosage.*

If you forget to take one dose of POLGYL, you must take the following dose normally.

In case you have additional questions about the use of this drug, please consult your doctor or pharmacist.

##### **Possible effects related to the termination of the treatment with POLGYL:**

No potential effect is expected related to the termination of metronidazole.

#### **4. Possible side effects**

Like all drugs, POLGYL also can cause adverse effects in individuals who are hypersensitive against any of the ingredients.

**Stop taking POLGYL in case of occurrence of any of the following and IMMEDIATELY inform your doctor or apply to the nearest emergency room:**

- Swelling in your hands, feet, joints, face or lips or in your throat that could result in respiratory distress or difficulties of swallowing. You might notice itchy rashes at the same time. This will show that you had developed an allergic reaction against POLGYL.
- A type of brain disorder called encephalopathy, which is very severe; however very rare, may be observed. The symptoms will vary; but, you can have fever, stiffness in your neck or headache, or you can hear non-existing sounds. At the same time, you can have difficulties in using your hands and feet or feel confused.

These are all very serious adverse effects.

If you experience any of these, you may need emergency medical intervention or hospitalization.

**In case you notice any of the following, immediately inform your doctor or apply to the nearest emergency room:**

- Yellow appearance in skin and eyes. This condition may indicate a liver disease (jaundice). In patients under treatment with metamizole together with other antibiotics, hepatic failure symptoms requiring liver transplantation have been reported.
- Unexpected infections, oral wounds, bruising, gum bleeding or fatigue. This condition may emerge as a result of a hematological problem.
- Severe abdominal pain reflecting to your back (pancreatitis)

These are all very serious adverse effects that may require emergency medical intervention.

These serious adverse effects are observed very rare.

**Inform your doctor if you notice any of the following:**

**Very rare (< 1/10,000)**

- Convulsions
- Mental problems including dizziness or hearing or seeing non-existing things (hallucinations)
- Rashes or redness on the skin
- Visual problems including blurred or double vision
- Decrease in visual acuity
- Changes in the color image
- Headache

- Dark urine
- Sleepiness or vertigo
- Pain in muscles or joints

**Unknown (Cannot be estimated based on the available data)**

- Numbness, tingling or pain or in limbs or fatigue
- Unpleasant taste in mouth
- Coated tongue, tongue discoloration/fuzz
- Nausea, vomiting, gastric discomfort or diarrhea
- Loss of appetite
- Pain around the stomach
- Fever
- Psychological breakdown
- Pain in the eyes (optic neuritis)
- Conglomeration of a group of signs including fever, headache, neck stiffness, over sensitivity against light, nausea and vomiting. This condition can be the result of the inflammation of the membrane covering the brain and medulla (meningitis).
- Blood living in and around the eyes, skin, swelling and rashes characterized by inflammation (Stevens-Johnson syndrome/erythema multiform)
- Serious illness characterized by fluid-filled blisters on the skin (toxic epidermal necrosis)

These are mild adverse effect of POLGYL.

*In case you encounter any adverse effects not mentioned in this patient information leaflet, please inform your doctor or pharmacists.*

**5. How to store POLGYL**

*Keep POLGYL in places out of sight and reach of children and within the original packaging.*

Store at room temperatures under 25°C and in a place without direct light.

**Use according to the expiry date.**

*Do not use POLGYL after the expiry date indicated on the package.*

*The expiry date will show the last day of that month.*

Do not dispose of expired or unused drugs! Give to the collection system determined by the Ministry of Environment and Urbanization.

***Marketing Authorisation Holder and Manufacturer:***

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