

## PATIENT INFORMATION LEAFLET

### NOVO-PLAN 1 g/2 ml Solution for I.M/I.V Injection

Administered intramuscularly or intravenously

Sterile

- **Active Substance:** Metamizol sodium 1000 mg
- **Excipients:** Injectable distilled water

**Before using this medicine, read all of this PATIENT INFORMATION LEAFLET carefully. Because, this leaflet includes important information for you.**

- *Keep this PATIENT INFORMATION 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.*
- *During the use of this medicine, tell that you are using this medicine when you go to a doctor or hospital.*
- *Follow the written instructions exactly. Do not use **higher or lower** dose than the recommended dose.*

#### **What is in this leaflet**

1. *What NOVO-PLAN is and what it is used for?*
2. *What you need to know before use NOVO-PLAN*
3. *How to use ANTOKSI- ?*
4. *Possible side effects*
5. *How to store NOVO-PLAN?*

#### **1. What NOVO-PLAN is and what it is used for?**

NOVO-PLAN contains metamizole sodium active substance. There is 1 g of metamizole sodium in one ampoule. One ampoule contains 2 ml of solution, and 1 ml of the solution contains 500 mg of active substance. It is available in packages containing 10, 50 and 100 ampoule.

NOVO-PLAN is a drug with pain relieving, antipyretic and spasm (contraction) resolving effects. Your doctor may have prescribed this form of NOVO-PLAN administered intravenously or intramuscularly, because you have severe or resistant pain or fever, and to relieve these symptoms in a short time.

#### **2. What you need to know before use NOVO-PLAN?**

**DO NOT use NOVO-PLAN in the following situations:**

- If you are allergic to metamizole sodium active substance contained in the drug or one of the other substances or drugs called pyrazolone (eg phenazone, propyphenazone) or pyrazolidine (eg phenylbutasone, oxyphenbutasone), you have developed a reaction that is manifested by abnormal reduction of cells
- If you have a disorder in your bone marrow function (eg if you have been treated for cancer) or if you have a disease in your body system that is responsible for making blood cells
- Against pain medications such as salicylates, paracetamol, diclofenac, ibuprofen, indomethacin, naproxen; if you have developed excessive allergic reactions such as inability to breathe, excessive itching and redness of the skin, hives, nasal mucosa, swelling

of the skin or respiratory tract.

- If you have a disease called acute intermittent hepatic porphyria (there may be a risk of initiating porphyria attacks.)
- If you have a baby less than three months old or weighing less than 5 kg
- If you have congenital glucose -6-phosphate dehydrogenase deficiency
- NOVO-PLAN should not be administered intravenously in infants between 3 and 11 months. It should not be administered intravenously or intramuscularly in patients with hypotension (low blood pressure).

### **USE NOVO-PLAN CAREFULLY in the following cases**

Administration of NOVO-PLAN intravenously or intramuscularly carries a higher risk of serious allergic reactions.

In case of fever, chills, sore throat, and mouth sores during treatment, stop the treatment immediately and contact the emergency room of the nearest hospital. This disorder (agranulocytosis), which is called granulocyte in the blood and is characterized by the excessive decrease of cells that play an important role in body defense, is an event of allergic origin that lasts at least a week and concerns the immune system. These reactions are very rare but can be severe and life threatening and can result in death. These are not dose-dependent and can occur at any time during treatment.

During treatment, general malaise, infection, fever, bruises, bleeding, paleness of the skin may be seen. These symptoms may have occurred due to a decrease in the number of all blood cells (pancytopenia). If you have one or more of these symptoms, discontinue treatment and contact your doctor immediately. In this case, your doctor will follow you by doing blood tests until the number of your blood cells returns to normal.

In particular, patients with the following conditions are at a particular risk for possible sudden and extreme severity allergic reactions to metamizole. Your doctor may ask you questions to find out if you have such a risk. If NOVO-PLAN is to be used under such risky conditions, strict medical supervision is required and the conditions for emergency treatment should be available.

- Patients with bronchial asthma,
- Patients with a large number of polyps in the nasal and sinus cavities,
- Patients with chronic urticaria,
- Patients who cannot tolerate (tolerate) alcohol; that is, patients who react even to a small amount of certain alcoholic beverages with symptoms such as runny nose, excessive tears in the eyes and pronounced redness of the eyes,
- Patients with intolerance (intolerance) to dyes (eg tartrazine) or preservatives (eg benzoates).

During treatment, life-threatening skin reactions, such as Stevens-Johnson syndrome (blisters filled with water on your skin or severe skin reaction that causes widespread redness and peeling), and toxic epidermal necrolysis (a serious disease with fluid-filled blisters on the skin) may occur. If you often develop fluid-filled blisters or skin rashes that become more and more severe in the mouth, discontinue treatment and contact your doctor immediately. These symptoms appear mostly in the first weeks of treatment. If you experience these symptoms, do not use NOVO-PLAN again.

Metamizole administration alone can cause excessive low blood pressure (isolated hypotensive reaction). Therefore, it is recommended to apply NOVO-PLAN very carefully and under medical supervision in the following cases:

- Patients with previously low blood pressure and disorders that may affect blood pressure control (patients who have lost excess fluid, patients with unstable circulation, circulatory failure)
- Patients with high fever
- Patients with severe coronary heart disease or blood vessels that nourish the brain (low blood pressure creates a risk.)
- Patients with kidney or liver disorders (the rate of excretion of metamizole from the body decreases.)

Please consult your doctor if these warnings apply to you, even at any time in the past.

### **Using NOVO-PLAN with food and drink**

This form of NOVO-PLAN is not taken orally. It is administered intravenously or intramuscularly.

### **Pregnancy**

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

You should not use NOVO-PLAN during the first and last trimester of your pregnancy. In the second trimester of your pregnancy, you should consult your doctor about using NOVO-PLAN and use it only if your doctor deems it appropriate.

*If you notice that you are pregnant during your treatment, consult your doctor or pharmacist immediately.*

### **Lactation**

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

If you need to be treated with NOVO-PLAN during breastfeeding, you need to stop giving milk to protect the baby from metamizole, which is excreted in breast milk. Do not breastfeed your baby for 48 hours after using NOVO-PLAN.

### **Ability to drive and use machines**

When used in high doses, metamizole may impair concentration and reaction ability. Do not drive or use machine, especially if you have used alcohol together.

### **Important information about some of the excipients contained in NOVO-PLAN**

It does not contain any auxiliary substances that require special precautions.

### **Use in combination with other drugs**

- Cyclosporine, which is used to suppress the immune system after organ transplants, can reduce cyclosporine levels when used together. Regular checks are required.
- When NOVO-PLAN is used with the drug called chlorpromazine used in the treatment of serious mental diseases, an excessive decrease in body temperature (hypothermia) can be seen.
- The drug group that includes NOVO-PLAN, oral anticoagulants (oral blood thinners), captopril

(high blood pressure medicine), lithium (a medicine used to treat manic depressive illness), methotrexate (a cancer, rheumatism or psoriasis treatment. drug) and triamteren (a diuretic drug). Although the effect of NOVO-PLAN on these drugs is unknown, caution should be exercised when using it together.

- NOVO-PLAN may increase the harmful effect of methotrexate on the blood when used with the drug called methotrexate used to treat cancer, rheumatism or psoriasis. These two drugs should not be used together.

- NOVO-PLAN can be dissolved in 5% glucose, 0.9% NaCl or ringer lactate solution. However, these solutions should be applied immediately as their stability is limited.

- Due to the possibility of incompatibility, metamizole sodium should not be administered with other injectable drugs.

- When the active ingredient of NOVO-PLAN metamizole is taken simultaneously, it can reduce the effect of acetylsalicylic acid (aspirin) on blood clotting. Therefore, this combination should be used with caution in patients using low-dose aspirin for heart protection.

- The active ingredient of NOVO-PLAN, metamizole bupropion (a drug used to treat mental depression and smoking cessation) can cause low blood levels. For this reason, caution is recommended in the simultaneous use of metamizole and bupropion.

*If you are currently taking or recently took any prescribed or over-the-counter drugs, please inform your physician or pharmacist.*

### **3. How to use NOVO-PLAN?**

**Instructions regarding correct use and dosage/administration frequency:  
NOVO-PLAN ampoule is definitely applied under the control of a doctor.**

Your doctor will determine the dose of your medicine and apply it to you depending on your illness.

NOVO-PLAN is generally used as follows:

In teens and adults aged 15 and over:

One-time dose to be administered intravenously or intramuscularly is 2-5 ml (1 NOVO-PLAN ampoule 2 ml or 2 NOVO-PLAN ampoule 2 ml).

The maximum daily dose can be increased to 10 ml (5 g) (5 NOVO-PLAN ampoule 2 ml).

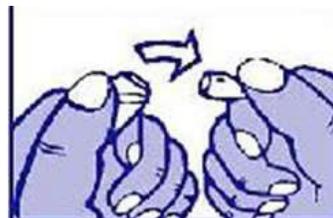
#### **Method of administration:**

NOVO-PLAN ampoules are administered by a healthcare professional who is trained in intravenous and intramuscular drug administration.

#### **Opening the Ampoule**



Hold the ampoule with the dot up. If there is a solution in the pull, tap the ampoule gently to let it flow down or shake the ampoule.



Hold the ampoule with the dot up, break the pull by pulling it down.

**Different age groups:****Usage in children:**

Your doctor will determine the dosage and method of administration depending on your child's age, body weight and disease.

**Usage in elderly**

Your doctor will adjust the dose considering the possible impairments in kidney and liver function in elderly patients and patients with general condition.

**Conditions of special use:****Renal and hepatic failure**

Your doctor will determine the dose of your medicine depending on your disease and the severity of your kidney/liver problems.

*Talk to your doctor or pharmacist if you have the impression that the effect of NOVO-PLAN is too strong or too weak.*

**If you use more NOVO-PLAN than you should:**

Since NOVO-PLAN will be used under the supervision of a doctor, necessary measures will be taken to prevent such a situation from developing. If this is the case, appropriate treatment will be given.

*If you use more NOVO-PLAN than you should, talk to a doctor or pharmacist.*

**If you forget to use NOVO-PLAN:**

Since NOVO-PLAN will be used under the supervision of a doctor, necessary measures will be taken to prevent such a situation from developing.

*Do not take a double dose to compensate forgotten dose.*

**If NOVO-PLAN treatment stopped, effects may occur:**

If you stop the NOVO-PLAN treatment without your doctor's approval, your pain may start again or your fever may increase.

**4. Possible side effects**

Like all other medicines, NOVO-PLAN may cause side effects in patients with hypersensitivity to any component of the drug.

**If one of following occurs, stop using NOVO-PLAN and tell your doctor immediately or consult nearest emergency room:**

- Skin rash, skin rash, or other symptoms on the skin or eyes, itching, shortness of breath, or high fever.
- If you become prone to bleeding, pin size bleeding under your skin
- If you have skin-filled blisters or severe skin reactions (Stevens-Johnson syndrome) that cause widespread redness and peeling.
- Kounis syndrome (an allergy-induced heart attack)

All of these are very serious side effects. If you have one of these, you have a serious allergy to

NOVO-PLAN.

You may need urgent medical attention or hospitalization.

All of these very serious side effects are very rare.

**If you notice any of the following, immediately tell your doctor or contact the emergency department of the nearest hospital:**

- Low blood pressure
- Urinary incontinence, especially in patients with kidney problems, a decrease in the amount of urine
- Urine blood and protein, high blood pressure, fever and swelling in the body (symptoms of acute interstitial nephritis)
- Vascular inflammation (phlebitis) in the application area (pain, bleeding, swelling)
- Sores in the mouth, pain and swelling in your throat, fever (may be a sign of agranulocytosis)
- General malaise, infection, non-falling fever, bruises, bleeding, pale skin. These symptoms may have occurred due to pancytopenia (a decrease in the number of all blood cells) that can result in death.
- Asthma attack that develops after medication (difficulty breathing, wheezing, increased number of breaths)

All these are serious side effects. Emergency medical attention may be required.

Serious side effects are very rare.

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

- Red color in urine
- Pain and regional reactions in the application area

These are mild side effects of NOVO-PLAN.

*Inform your doctor or pharmacist if you encounter any side effects not mentioned in this instructions for use.*

#### **5. How to store NOVO-PLAN ?**

*Store NOVO-PLAN in its packaging and keep out of the reach and sight of children.*

Store at room temperature under 25°C and its original package.

**Use in accordance with expiration dates.**

*Do not use NOVO-PLAN after the expiration date on the packaging.*

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

***Marketing Authorization Holder:***

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