**Patient information leaflet**

**MUSCUREL®**

*Thiocolchicoside 8 mg, capsule*

**Read all of this leaflet carefully before you start taking this medicine because it contains important information for you. If you notice side effects not mentioned in this leaflet, it is advised to notify the doctor or healthcare professional. Do not pass this medicine on to others.**

1. **What is Muscurel® and what is it used for**

This medicine is a muscle relaxant: myorelaxant, ATC code: M03BX05. **When to use Muscurel®?** It is used in adults and adolescents 16 years of age and older as an add-on therapy for painful muscle contractures and for acute painful conditions related to the spine.

**2. What you need to know before you take Muscurel®:**. **Do not take Muscurel®:** if you are allergic (hypersensitive) to thiocolchicoside, to colchicine, **to carmoisine** or to any of the other ingredients of this medicine (listed in Section 6); if you are pregnant, might become pregnant, or believe you might be pregnant; if you are a woman of childbearing age who is not using contraceptives; if you are breast-feeding. If you are not sure, it is essential that you check with your doctor or pharmacist. **Warnings and precautions:** Talk to your doctor or pharmacist before taking Muscurel®. In case of diarrhoea, tell your doctor and he/she may readjust your dosage. Before you start taking this medicine, tell your doctor if you have, or have had, any seizures or epilepsy; your doctor is best qualified to assess the risk-benefit ratio of thiocolchicoside and to increase your clinical monitoring. In case you have a seizure, stop your treatment and tell your doctor immediately. If you have the following symptoms during treatment with this medication: loss of appetite, nausea or vomiting, abdominal discomfort, unexplained fatigue, dark-coloured urine, jaundice, pruritus or itching; stop taking Muscurel® and contact your doctor or health care professional immediately.

Follow the dosage and treatment length exactly as recommended in Section 3. Do not use this medicine at a higher dose (not more than 16mg/day) or for more than 7 days. This is because the substances that will form inside your body when you take thiocolchicoside at high doses may cause lesions to certain cells (abnormal number of chromosomes). **Children and adolescents** : For safety reasons, do not give this medicine to children or adolescents less than 16 years of age. **Other medicines and Muscurel®:** Tell your doctor or pharmacist if you are taking, have recently taken, or might take any other medicines. **Pregnancy :** Do not take this medicine if you are pregnant, might become pregnant, or believe you might be pregnant; if you are a woman of childbearing age who is not using contraceptives. This medicine may be life-threatening to your unborn child. **Breast-feeding :** Do not take this medicine if you are breast-feeding, as this medicine passes into breast milk. **Fertility :** This medicine may cause male fertility problems through the potential alteration of sperm cells (abnormal number of chromosomes) especially at doses exceeding 16 mg per day (see under Section 2, “Warnings and precautions”). **Driving and using machines :** This medicine may frequently cause drowsiness. You should consider this before driving or using a machine. Your drowsiness will increase if you take alcohol or medicines containing alcohol during the treatment. **Important information about some ingredients :** Muscurel® contains lactose monohydrate**:** contact your doctor if you have any sugar intolerance. The capsule of Muscurel® contains carmoisine (E122).

**3. How to take Muscurel®**Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. The recommended and maximum dose is 8mg every 12 hours (i.e. 16mg per day). The maximum length of treatment is limited to 7 consecutive days. Do not exceed the recommended dose or treatment length. This medicine should not be used for long-term treatment (see Section 2, “Warnings and precautions”). **Use in children and adolescents:** For safety reasons, do not give this medicine to children or adolescents less than 16 years of age. **If you take more Muscurel® than you should:** immediately contact your doctor or pharmacist. **If you forget to take a Muscurel® capsule:** do not take a double dose to make up for a forgotten dose. If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

**4. Possible side effects** Like all medicines, this medicine can cause side effects, although not everybody gets them. *Common:* digestive disorders such as diarrhoea and stomach pain (if these effects occur, tell your doctor); drowsiness. *Uncommon:* digestive disorders such as nausea and vomiting (if these effects occur, tell your doctor); skin reactions such as itching, redness, bumps, vesicles or blisters on the skin. *Rare:* an allergic reaction such as hives. *Undetermined frequency:* an allergic reaction such as angioedema (sudden swelling of the neck and face, possibly causing difficulty breathing); anaphylactic shock (a serious, life-threatening allergic reaction involving abrupt malaise and a major drop in blood pressure, possibly preceded by an eruption of bumps, itching, redness of the skin, difficulty breathing, swelling of the face and/or neck); seizures or relapsed attacks in epileptic patients (see “Warnings and precautions” Section); a liver condition (hepatitis) (see “Warnings and precautions” Section). If any of these effects occur, stop taking the medicine and contact your doctor immediately. This also includes any possible side effects not listed in this leaflet.

**5. How to store Muscurel®:** Store below 30°C. Keep out of reach and sight of children. Do not use after the expiry date, stated on the packaging (Exp.). The expiry date refers to the last day of that month.Do not throw away any medicines via wastewater or household waste. Ask your pharmacist for advice. These measures will help protect the environment.

**6. Contents of the pack and other information: What Muscurel® contains:** The active ingredient is thiocolchicoside. One capsule contains 8mg of thiocolchicoside. The other ingredients are: lactose monohydrate, maize starch, magnesium stearate; the capsule shell contains gelatine, purified water, sodium laurylsulfate (E487), titanium dioxide (E171), indigo carmine (E132), carmoisine (E122). **What Muscurel® looks like and contents of the pack:** Cardboard box with one transparent PVC/Al blister package of 10 capsules. Each capsule, with a transparent body and dark purple head, contains a yellow powder. **Muscurel® is a prescription only medicine**. **Manufacturer:** Bilim Ilaç San. Ve Tic A.Ş. Gebze Organize Sanayi Bölgesi 1900 Sokak No: 1904 41480 Gebze, Kocaeli, Turkey. **Marketing authorisation holder:** Dafra Pharma GmbH, Mühlenberg 7, 4052 Basel, Switzerland. This leaflet was last revised: 05/2020