Patient Leaflet According to the Pharmacists' Regulations (Preparations) – 1986

This medicine is sold without a doctor's prescription

Arthryl® Go Sachets
Powder for Oral Solution

Active ingredient:
Crystalline Glucosamine Sulfate 1884 mg (equivalent to glucosamine sulfate 1500 mg, sodium chloride 384 mg).
For a list of the other ingredients, see section 6.
See also 'Important information about some of the medicine's ingredients' in section 2.

Read this entire leaflet carefully before using the medicine.
This leaflet contains concise information about the medicine. If you have any further questions, please refer to your doctor or pharmacist.
Use this medicine according to the instructions in the dosage section in this leaflet. Consult the pharmacist if you require additional information.
Contact the doctor if the symptoms worsen, or do not start to improve after 30 days.

1. What is the medicine intended for?

Arthryl® Go is intended for the relief of symptoms in mild to moderate osteoarthritis of the knee.
Therapeutic group: non-steroidal anti-rheumatic medicines.

2. Before using the medicine

Do not use the medicine if:

- You are sensitive (allergic) to the active ingredient (glucosamine) or to any of the other ingredients the medicine contains (for a list of the other ingredients, see section 6).
- You are sensitive (allergic) to seafood.

Special warnings regarding the use of this medicine:
Before the treatment with Arthryl® Go (and during it), tell your doctor if:

- You suffer from diabetes or from glucose intolerance. Closer monitoring of blood sugar levels and insulin intake (if relevant) may be required at the beginning of the treatment and periodically throughout it.
- You suffer from asthma. When starting the treatment with the medicine, it is possible that there will be a worsening of the asthma symptoms.
- You suffer from a severe liver or kidney problem.
- You have high blood cholesterol levels.
- You have intolerance to some sugars.
- You are on a low sodium diet.

Additional warnings:

- The presence of another joint disease, which would require alternative treatment, should be excluded.
- If additional symptoms appear or you experience a change in the existing symptoms, consult your doctor immediately.

Children and adolescents: This medicine is not intended for children and adolescents under 18 years of age since its safety and efficacy have not been determined in this age group.

Tests and follow-up: Some patients may require medical follow-up.

Drug interactions:
If you are taking, or have recently taken any other medicines, including non-prescription medicines and nutrition supplements, please tell your doctor or pharmacist. Especially inform your doctor or pharmacist if you are taking the following medicines (it should be noted that the following list indicates the active ingredients in the medicines. If you are unsure whether you are using one of these medicines, please consult with your doctor or pharmacist):

- Some anticoagulants of the coumarin group (e.g. warfarin, dicoumarol, phenprocoumon, acenocoumarol, fluindione) – their effect may be stronger if used concomitantly with Arthryl® Go. When initiating or ending Arthryl® Go therapy, closer monitoring of blood coagulation function may be required.
- Antibiotics of the tetracycline group – Arthryl® Go may increase their absorption.

Use of this medicine and food: It is preferable to take this medicine with a meal.

Pregnancy and breastfeeding: Do not use the medicine if you are pregnant or breastfeeding.

Driving and use of machinery: If you experience a headache, drowsiness, tiredness, dizziness or visual disturbances, do not drive or operate machinery.

Important information about some of the medicine's ingredients:

- Each Arthryl® Go sachet contains 2.5 mg aspartame, which is a source of phenylalanine and may harm people suffering from phenylketonuria.
- Arthryl® Go contains sorbitol (a type of sugar). If you suffer from intolerance to some sugars, consult your doctor before taking this medicine. (Each sachet contains about 2 g sorbitol).
- The medicine contains 151 mg sodium in each sachet. This quantity is equivalent to 7.5% of the maximum recommended adult daily sodium intake (2 g). Consult your doctor if you are on a low sodium diet.

3. How to use this medicine?

You should check with your doctor or pharmacist if you are not sure regarding the dosage and the manner of treatment with the medicine.
The standard dosage and instructions for use are usually:
Dissolve the contents of one sachet in a glass of water and drink immediately after preparation, once daily, preferably with a meal.
Do not exceed the recommended dose.

Attention:
This medicine is intended for use only after complete dissolution of the powder in a glass of water.
Do not take the powder before it is dissolved in a glass of water.

- The medicine is not intended for treatment of acute pain symptoms. Relief of symptoms (especially pain relief) may be experienced only after a few weeks.
- If no relief of symptoms is experienced after a treatment period of 2 to 3 months, continued treatment with Arthryl® Go should be re-evaluated in consultation with the doctor.
- If the symptoms worsen after starting the treatment, consult your doctor.

The pain relieving effect of Arthryl® may start only after a week or two. If you suffer from pain during the treatment, and especially in the beginning of treatment, you can take in addition a nonsteroidal analgesic (NSAIDs).

Use in patients with impaired kidney and/or liver function: since no studies have been carried out in these groups, no dosage recommendation can be made.

If you have accidentally taken a higher dosage: if you have taken an overdose or if a child has accidentally swallowed the medicine, proceed immediately to a doctor or a hospital emergency room and bring the package of the medicine with you.
If you forgot to take the medicine, skip the forgotten dose and take the next dose at its regular time. Do not take a double dose to make up for the forgotten dose.

If you stop taking the medicine, the symptoms may return.

Do not take medicines in the dark! Check the label and the dose each time you take a medicine. Wear glasses if you need them.
If you have further questions concerning the use of the medicine, consult your doctor or pharmacist.

4. Side effects

Like any medicine, the use of Arthryl® Go may cause side effects in some users. Do not be alarmed while reading the list of side effects, you may not suffer from any of them.

Stop the treatment and refer to the doctor immediately in the following cases:

- If symptoms of allergic reactions (hypersensitivity), for example a skin rash or itching, occur. In some patients the reaction may be severe.

Additional side effects:
Common side effects (appear in 1-10 users out of 100):
Headache, drowsiness/somnolence, tiredness, diarrhea, constipation, nausea, flatulence in the digestive tract, abdominal pain, indigestion.
Uncommon side effects (appear in 1-10 users out of 1,000):
Redness of the skin, flushing, itchiness, skin inflammation (manifested for example as a rash).
Side effects of unknown frequency (effects whose frequency has not been determined yet):
Allergic reaction, dizziness, visual disturbances, difficulty sleeping (e.g. difficulty in falling asleep or remaining asleep), irregular heartbeat or changes in heart rate, poor control of diabetes, increase in blood sugar level (glucose), asthma/worsening of asthma, vomiting, excess fluid in the tissues (edema), angioedema, hives (a type of rash), increase in certain liver enzymes, jaundice (yellowing of the skin and/or whites of the eyes), increase in blood pressure, fluctuations in INR (a blood coagulation index), high blood cholesterol.

If a side effect appears, if any of the side effects worsens, or you suffer from a side effect not mentioned in this leaflet, consult your doctor.

Side effects may be reported to the Ministry of Health by clicking on the link "Report on side effects following medicinal treatment" on the homepage of the Ministry of Health website (www.health.gov.il) which leads to an online form for reporting side effects, or by entering the link: https://sideeffects.health.gov.il/

5. How to store the medicine?

- Avoid poisoning! This medicine, and any other medicine, must be stored in a closed place out of the reach and sight of children and/or infants, to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.
- Do not use the medicine after the expiry date (exp. date) stated on the package. The expiry date refers to the last day of that month.
- Storage conditions: store below 25°C.

6. Additional information

In addition to the active ingredient, the medicine also contains:
Sorbitol, citric acid anhydrous, macrogol 4000, aspartame.

What does the medicine look like and what does the package contain?
White, crystalline, odorless powder contained in single dose sachets. Each box contains 30 sachets.

Registration holder: Dexcel® Ltd., 1 Dexcel St., Or Akiva 3060000, Israel.

Manufacturer: Rottapharm Ltd., Ireland.

Medicine registration number in the National Medicines Registry of the Ministry of Health: 1547034599

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