Patient information leaflet (package leaflet)

Trade name: KHONDRA-JECT, 100 mg/ml

International non-proprietary name: chondroitin sulfate

Pharmaceutical form: solution for injection

Description
Clear, colorless or slightly yellowish solution with benzyl alcohol odour.

Composition per ampoule
Active substance: each 1 ml ampoule contains 100 mg of sodium chondroitin sulfate;
each 2 ml ampoule contains 200 mg of chondroitin sulfate sodium;
excipients: benzyl alcohol, sodium metabisulphite, sodium hydroxide, water for injection.

Pharmacotherapeutic group: anti-inflammatory and antirheumatic agents. Nonsteroidal anti-inflammatory and antirheumatic agents. Chondroitin sulfate.
ATC code: M01AX25

Pharmacological properties
Pharmacodynamic properties
Mechanism of action
A high molecular weight mucopolysaccharide that affects metabolic processes in hyaline cartilage. Reduces degenerative changes in the cartilaginous tissue of the joints, accelerates the processes of its recovery, stimulates the synthesis of proteoglycans.
When treated with the medicinal product, pain decreases and the mobility of the affected joints improves. In the treatment of degenerative changes in the joints with the development of secondary synovitis, a positive effect can be observed already 2-3 weeks after the start of the administration: pain in the joints decreases, the clinical manifestations of reactive synovitis disappear, and the range of motion in the affected joints increases. The therapeutic effect persists for a long time after the end of the course of treatment.

Pharmacokinetic properties
Absorption
The maximum concentration (C_{max}) of chondroitin sulfate in plasma is reached after 1 hour, then gradually decreases over 2 days.
For intramuscular administration, C_{max} is reached after 48 hours and is 77.1-114.3 ng/ml, with a single intra-articular injection at a dose of 200 mg, plasma C_{max} of chondroitin sulfate is observed after 1-2 hours and is 52.5-86.9 ng/ml
Distribution
After intramuscular administration chondroitin sulfate is rapidly distributed. Already 30 minutes after the injection, it is found in the blood in significant concentrations. Chondroitin sulfate accumulates mainly in the cartilaginous tissue of the joints. The synovial membrane is not an obstacle to the penetration of the medicinal product into the joint cavity. Experiments have shown that 15 minutes after intramuscular injection of chondroitin sulfate is found in the synovial fluid, then penetrates into the articular cartilage.

With intra-articular administration, chondroitin sulfate is retained in the tissues of the joint and its gradual release into the bloodstream.
Elimination
The half-life ($T_{1/2}$) with intramuscular injection is 2.2 hours, with intraarticular administration - 2.5 hours.

Therapeutic indications
Degenerative-dystrophic diseases of the joints and spine:
- osteoarthritis of peripheral joints;
- intervertebral osteochondrosis and osteoarthritis.
To accelerate the formation of callus in fractures.

Contraindications

- hypersensitivity to the medicinal product or its components;
- hemorrhage and hemorrhagic tendency;
- thrombophlebitis;
- with intraarticular injection: the presence of active inflammatory or infectious processes in the joint, the presence of an active skin disease or skin infection in the area of the proposed injection;
- children and adolescents up to 18 years of age;
- pregnancy and lactation.

Posology and method of administration
The medicinal product is prescribed intramuscularly at 100 mg every other day. With good tolerance, the dose is increased to 200 mg, starting with the fourth injection. The course of treatment is 25-30 injections. If necessary, after 6 months, a second course of treatment is possible.
In osteoarthritis of large joints, a combination of intra-articular and intramuscular routes of administration is possible. Spend up to 5 intra-articular injections of 200 mg with a break of 3 days between injections and 16 intramuscular injections of 200 mg with an interval of 1 day between injections (every other day).
Intra-articular administration of the drug is carried out under aseptic conditions by a specialist who has been trained in the technique of intra-articular administration. Depending on the size of the joint, up to 2 ml of KHONDRA-JECT can be injected into the joint cavity. After intra-articular injection of the drug, the puncture site is smeared with an alcohol wipe, a bactericidal patch is applied.
For the formation of callus, the course of treatment is 3-4 weeks (10-14 injections intramuscularly every other day).

Undesirable effects
Immune system disorders: allergic reactions (pruritus, erythema, urticaria, dermatitis).
General disorders and administration site conditions: hemorrhages at the injection site.

Special warnings
The composition of the medicinal product includes sodium metabisulphite, which occasionally can cause severe hypersensitivity reactions and bronchospasm.
1 ml of the medicinal product contains 9 mg of benzyl alcohol, which can cause toxic and allergic reactions in infants and children under 3 years of age.

This medicinal product contains less than 1 mmol (23 mg) sodium per 1 ml, which means it is essentially sodium-free.

Pregnancy and lactation
There are currently no data on the safety of the medicinal product. It is not recommended to use KHONDRA-JECT during pregnancy and breastfeeding.

Overdose
Currently, cases of overdose of chondroitin sulfate have not been reported.

Interaction with other medicinal products
The product may increase the effect of indirect anticoagulants, antiplatelet agents, fibrinolytics, which requires more frequent monitoring of blood coagulation parameters when used concomitantly.

Effects on ability to drive and use machines
KHONDRA-JECT does not affect the ability to drive vehicles and work with mechanisms.

Pharmaceutical form and presentation
Solution for intramuscular and intraarticular administration, 100 mg/ml.
1 ml or 2 ml in colorless neutral glass ampoules with a colored break ring or with a colored dot and a notch. One, two or three colored rings and/or two-dimensional barcode and/or alphanumeric coding or without additional color rings, two-dimensional barcode, alphanumeric coding are additionally applied to the ampoules.
5 ampoules in a blister pack made of PVC film and polymer film or without film.
2 blister packs together with patient information leaflet in a carton.

Shelf life
3 years. Do not use after the expiration date.

Storage conditions
Protect from light at a temperature below 25ºC.
Keep out of the reach of children.

Prescription status
On prescription.