

Prednisolona 10mg

Sodium Phosphate Injection USP

Composition: Each ml contains:
Prednisolone Sodium Phosphate USP
equivalent to Prednisolone Phosphate 5 mg
Water for Injection USP q.s.

Therapeutic indications

This medicinal product is indicated in adults for the local treatment, via intra-articular or periarticular injection, of the following conditions: rheumatoid arthritis; osteoarthritis; non-infectious synovitis; tennis elbow; golfer's elbow; and bursitis.

This medicinal product is also suitable for intramuscular administration in conditions requiring systemic corticosteroids, for example: suppression of inflammatory and allergic disorders such as bronchial asthma, anaphylaxis, ulcerative colitis, and Crohn's disease.

Posology and method of administration

Posology

Undesirable effects may be minimized by using the lowest effective dose for the shortest possible duration and by administering the daily requirement as a single morning dose or, whenever possible, as a single morning dose on alternate days. Frequent patient review is required to titrate the dose against disease activity.

Pediatric population

This medicinal product is not suitable for use in children.

Elderly

Steroids should be used with caution in the elderly, as the risk of adverse effects increases with age.

Method of administration

Intra-articular, periarticular, or intramuscular injection.

Adults

For articular use: 5–10 mg, depending on the size of the joint. Injections may be repeated upon relapse. No more than three joints should be treated in a single day.

For intramuscular use: The dosage may range from 10 to 100 mg, administered once or twice weekly as required. It will depend on the disease, its severity, and the clinical response to the drug. The maximum dosage should not exceed 100 mg twice weekly.

Contraindications

Hypersensitivity to the active substance or to any of the excipients.
Systemic infections, unless specific anti-infective treatment is administered.
Vaccination with live vaccines.
Patients with ocular herpes simplex, due to the risk of perforation.
Intra-articular and periarticular injections of this medicinal product when the joint or

surrounding tissues are infected.

Injection into tendon sheaths and bursae when infection is present.

Injection directly into tendons.

Injection into the spine or other non-diarthrodial joints.

Fertility, pregnancy, and lactation

Pregnancy

The ability of corticosteroids to cross the placenta varies among the drugs. However, 88% of prednisolone is inactivated as it crosses the placenta.

Administration of corticosteroids to pregnant animals can cause fetal developmental abnormalities, including cleft palate, intrauterine growth retardation, and effects on brain growth and development. There is no evidence that corticosteroids result in an increased incidence of congenital anomalies, such as cleft palate/cleft lip, in humans. However, when administered for prolonged periods or repeatedly during pregnancy, corticosteroids may increase the risk of intrauterine growth retardation. Hypoadrenalism may, in theory, occur in the newborn following prenatal exposure to corticosteroids, but it usually resolves spontaneously after birth and is rarely clinically significant. As with all medicines, corticosteroids should be prescribed only when the benefits to mother and child outweigh the risks. However, when corticosteroids are essential, patients with normal pregnancies may be treated as if they were not pregnant.

Patients with pre-eclampsia or fluid retention require careful monitoring. Suppression of hormone levels has been reported during pregnancy, but the significance of this finding is unclear.

Breastfeeding

Corticosteroids are excreted in small amounts in breast milk. However, doses of up to 40 mg of prednisolone per day are unlikely to cause systemic effects in the infant. Infants of mothers taking doses higher than this may experience some degree of adrenal suppression, but the benefits of breastfeeding likely outweigh any theoretical risk. Monitoring the infant for adrenal suppression is recommended.

Overdose

Management

Overdose is unlikely with this medicine, but no specific antidote is available. Treatment should be symptomatic.

Storage:

Store at or below 25°C. Protect from light.

Presentation: Box containing 50 ampoules of 2 ml.

Manufactured in India:

