SERTOSPAN
Suspension for Injection
Sterile suspension

For intramuscular, intra-articular, peri-articular, intralesional and soft tissue injection.

- ***Drug Substance****:*

  Betamethasone dipropionate 6.43 mg (equivalent to 5.0 mg Betamethasone)

  Betamethasone sodium phosphate 2.63 mg (equivalent to 2.0 mg Betamethasone)

Excipients: Disodium edetate, sodium phosphate; dibasic anhydrous, sodium chloride,

polysorbate 80, hydrochloric acid (for pH adjusting), benzyl alcohol, methylparaben (E218),

propylparaben (E216), sodium carboxymethyl cellulose (25-50 cps), polyethylene glycol 3350, water for injection

Read all of this LEAFLET carefully before you start taking this medicine, it includes special information for you.

- *Keep this 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.*
- *If you go to doctor or hospital at the time of using this medicine,*

please tell your doctor.

- *Please follow the instructions exactly. Do not use another **high or low***

***doses** out of recommended.*

In this leaflet:

1. WHAT IS SERTOSPAN AND WHAT IT IS USED FOR?

SERTOSPAN is slightly viscous liquid containing white particles easily suspended and no foreign substance.

SERTOSPAN is presented in 2 ml ampoules.

SERTOSPAN is in the ampoule form containing 6.43 mg Betamethasone dipropionate equivalent to 5.0 mg Betamethasone

and 2.63 mg Betamethasone sodium phosphate equivalent to 2.0 mg Betamethasone as active ingredients.

These substances belong to class of **corticosteroids.**

SERTOSPAN is for tissue injection (muscle, articular). SERTOSPAN should not be administered intravenously or subcutaneously.

SERTOSPAN Suspension for Injection is indicated for the treatment of acute and chronic corticosteroid-responsive disorders such as the following conditions:

- Articular diseases such as reumatoid arthritis, osteoarthritis and rheumatic diseases
- Musculoskeletal system disorders (i.e, bursitis, tendinitis)
- Allergic situations such as asthma, allergic rhinitis, angioedema
- Allergic skin disesases such as eczema, psoriasis, urticaria
- Hormonal disorders
- Immune system disorders (i.e., collagen tissue disease)

2. BEFORE YOU USE SERTOSPAN

Do not use SERTOSPAN if :

- If you have common fungus diseases (systemic)

- If you are allergic (hypersensitive) to betamethasone dipropionate, betamethasone sodium phosphate or other corticosteroid class drugs or any of the other ingredients of SERTOSPAN.

Take special care with SERTOSPAN if:

- you have severe infection, surgery or injury
- you have ocular herpes
- you have hypothyroidism and cirrhosis.
- you have emotional instability or psychotic tendencies
- you have hypoprothrombinemia, aspirin should be used cautiously in conjunction with corticosteroids
- there is a probability of impending perforation (ulcerative colitis), abscess, or other pyogenic infection; diverticulitis; fresh intestinal anastomoses; active or latent peptic ulcer; renal insufficiency; hypertension; osteoporosis; and myasthenia gravis, corticosteroids should be used with caution in nonspecific ulcerative colitis
- corticosteroids may mask signs of infection. Prolonged corticosteroid use may produce posterior subcapsular cataracts, glaucoma with possible damage to the optic nerves, and may enhance the establishment of secondary ocular infections due to fungi or viruses.
- when used in large doses synthetic corticosteroid derivatives may result in elevation of blood pressure, and salt and fluid retention and increased potassium excretion.
- while on corticosteroid therapy, patients should not be vaccinated against smallpox. Other immunization procedures should not be undertaken in patients receiving corticosteroids, especially high doses. You should tell your doctor if you are vaccinated.
- you have tuberculosis
- In children and babies
- Corticosteroid therapy may alter the motility and number of spermatozoa

- You have history of drug allergy, talk to your doctor since rare instances of anaphylactoid reactions have occurred with parenteral corticosteroid therapy.

With long-term corticosteroid therapy, transfer from parenteral to oral administration should be considered after weighing the potential benefits and risks. Ask your doctor before taking this medicine by oral administration.

If you have any of these conditions even at any time in the past, please consult your doctor.

Using SERTOSPAN with food and drink

The effect of SERTOSPAN is not influenced by food and drink.

Pregnancy

Ask your doctor or pharmacist before taking this medicine.

SERTOSPAN should not be used during pregnancy if not necessary. The use of corticosteroids during pregnancy, in nursing mothers, or women of childbearing potential requires that the possible benefits of the drug be weighed against the potential hazards to the mother and fetus or infant.

Infants born of mothers who have received substantial doses of corticosteroids during pregnancy should be carefully observed for signs of hypoadrenalism.

Since transplacental passage of corticosteroids occurs, newborn and young infants born of mothers who were dosed with corticosteroids throughout most or some portion of their pregnancy should be examined carefully for the possible very rare occurrence of congenital cataracts.

Consult your doctor if you realize that you are pregnant while using this medicine.

Breast-feeding

Ask your doctor or pharmacist before taking this medicine.

Corticosteroid may exist in human milk therefore, If you are breast-feeding, do not use SERTOSPAN or if you continue to use SERTOSPAN you should stop breastfeeding.

Driving and using machines

SERTOSPAN has no effect on ability to drive and use machines.

Important information about some of the ingredients of SERTOSPAN

SERTOSPAN is essentially 'sodium free' as it contains less than 1 mmol sodium (23 mg).

Propylparaben (E216) and methylparaben (E218) present in this medicinal product may result in allergic reactions and bronchospasm.

Sertospan contains 9.00 mg benzyl alcohol in each 1 ml ampoules. It should not be administered to premature babies and new born babies. It may result in toxic and allergic reactions in babies and children up to 3 year age.

Using with other medicines

Concurrent use of phenobarbital, rifampin, phenytoin or ephedrine may enhance corticosteroid metabolism, thus reducing therapeutic effects. Excessive corticosteroid effects may occur in patients receiving both a corticosteroid and an estrogen.

Concurrent use of corticosteroids with potassium-depleting diuretics may enhance hypokalemia.

Concurrent use of corticosteroids with cardiac glycosides may enhance the possibility of arrhythmias or digitalis toxicity associated with hypokalemia.

Corticosteroids may enhance the potassium depletion caused by amphotericin B.

Concurrent use of corticosteroids with coumarin-type anticoagulants may increase or decrease the anticoagulant effects,

possibly requiring adjustment in dosage.

Combined effects of nonsteroidal anti-inflammatory drugs or alcohol with glucocorticoids may result in

an increased occurrence or increased severity of gastrointestinal ulceration. Corticosteroids may decrease blood salicylate concentrations.

When corticosteroids are given to diabetics, dosage adjustments of the antidiabetic drug may be necessary.

Concomitant glucocorticoid therapy may inhibit the response to somatotropin. During somatotropin treatment.

Please tell your doctor if you are taking or have recently taken any other medicines, including

medicines obtained without prescription, because they might interact.

Drug/Laboratory Test Interactions

Corticosteroids may affect the nitroblue tetrazolium test for bacterial infection and produce false negative results.

You should tell your doctor ın case of having test.

3. HOW USE SERTOSPAN

Posology and method of administration:

SERTOSPAN will be given to you by a doctor or nurse.

SERTOSPAN is recommended for:

- Intramuscular injection in conditions responsive to systemic corticosteroids
- Injection directly into the affected soft tissues where indicated
- Intra-articular and peri-articular injection in arthritis
- Intralesional injection in various dermatologic conditions
- Local injection in certain inflammatory and cystic disorders of the foot and soft tissue

SERTOSPAN SUSPENSION IS NOT FOR INTRAVENOUS OR SUBCUTANEOUS USE.

Avoid injecting corticosteroids directly into tendons.

Strict aseptic technique is mandatory in use of SERTOSPAN Suspension.

Route and method of administration:

Your doctor will decide on dosage and frequency of administration depending on the severity of disease.

Dosing requirements are variable and must be individualized on the basis of the specific disease,

the severıty of the condition and the response of the patient.

The initial dose should be maintained or adjusted by your doctor until a satisfactory response is observed.

If a satisfactory clinical response does not occur after a reasonable period of time, treatment with SERTOSPAN Suspension

should be discontinued and other appropriate therapy initiated.

If you notice effect of SERTOSPAN that is strong or weak, tell your doctor or pharmacist

If you use more SERTOSPAN than you should

Including betamethasone, a single overdose of a corticosteroid would not be expected to produce acute symptoms.

Except specific conditions including diabetes mellitus, glaucomal, active peptic ulcer, intake of digital, coumarin type

anticoagulant or diuretic causing potassium loss, use of corticosteroids at high doses for a few days does not produce severe results.

If you think you have been given too much SERTOSPAN tell your doctor, pharmacist or nurse immediately.

If you forget to take SERTOSPAN

If you forget to take Sertospan, use as soon as you remember, and then go back to your regular routine.

Do not take a double dose to make up for a forgotten dose of SERTOSPAN.

If you stop taking SERTOSPAN

Following cessation of long-term or high-dose corticosteroid therapy, monitoring may be necessary for up to one year.

Drug-induced secondary adrenocortical insufficiency may result from too rapid corticosteroid withdrawal and may

be minimized by gradual dose reduction. The lowest possible dose of corticosteroid should be used to control the condition

under treatment. When dose reduction is possible, the reduction should be gradual. Therefore, do not stop taking SERTOSPAN

immediately and follow the instructions of your doctor.

4. POSSIBLE SIDE EFFECTS

Like all medicines, SERTOSPAN can cause side effects, although not everybody gets them.

Intra-articular administration may produce systemic as well as local effects.

Side effects are related to dosage and duration of treatment.

Adverse reactions of SERTOSPAN Suspension can usually be reversed or minimized by a

reduction in dosage; this is generally preferable to withdrawal of drug treatment.

Systemic side effects are similar side effects with corticosteroid use.

Tell a doctor or nurse straight away if any of the following side effects happen. You may need urgent medical treatment:

- Swelling of face
- Blindness: rare instances of blindness associated with intralesional therapy around the face and head
- Headache and nausea

These are all serious adverse effects. Emergency medical intervention or hospitalization may require.

If you experience any of following side effects, contact your doctor:

- Changes in skin pigmentation (hyperpigmentation or hypopigmentation)
- Thinning of the skin (subcutaneous and cutaneous atrophy)
- post-injection flare (following intra-articular use)
- Charcot-like arthropathy.

These are all mild adverse effects of SERTOSPAN.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE SERTOSPAN

Keep out of the reach and sight of children.

Do not use SERTOSPAN after the expiry date. The expiry date refers to the last day of that month.

Store below 25ºC. Keep in room temperature. Do not freeze. Store in original packaging.

''Do not use SERTOSPAN if the package is open or torn''

THE FOLLOWING INFORMATION IS INTENDED FOR MEDICAL OR HEALTHCARE PROFESSIONALS ONLY

SERTOSPAN Suspension contains two betamethasone esters, one of which, betamethasone sodium phosphate,

disappears rapidly from the injection site. The potential for systemic effect produced by this soluble portion of SERTOSPAN

Suspension should therefore be taken into account by the physician when using this preparation. Corticosteroid effect is enhanced

in patients with hypothyroidism and in those with cirrhosis. Since complications of glucocorticoid treatment are dependent on dose size

and duration of treatment, a risk/benefit decision must be made in each individual case.

With long-term corticosteroid therapy, transfer from parenteral to oral administration should be considered after weighing the potential benefits and risks.

Method of administration:

The small crystal size of betamethasone dipropionate permits the use of a finegauge needle (up to 26 g) for intradermal and intralesional administration.

Concomitant use of local anesthetic is rarely necessary. If coadministration of a local anesthetic is desired, SERTOSPAN Suspension may

be mixed (in the syringe) with 1% or 2% procaine hydrochloride or lidocaine, using formulations which do not contain parabens.

Similar local anesthetics may also be used. Anesthetics containing methylparaben, propylparaben, phenol, etc. should be avoided.

The required dose of SERTOSPAN Suspension is first withdrawn into the syringe. The local anesthetic is then drawn in, and the syringe is shaken briefly.

An intradermal dosage of 0.2 ml/cm2 of SERTOSPAN Suspension evenly injected with a tuberculin syringe and a 26-gauge needle

is recommended. The total Amount of SERTOSPAN Suspension injected at all sites each week should not exceed 1 ml.

A tuberculin syringe with a 25-gauge needle is suitable for most injections.

Intramuscular corticosteroid administration should be given deep into large muscle masses

to avoid local tissue atrophy. Soft-tissue and intralesional corticosteroid injections may produce systemic and local effects.

Intra-articular administration:

Examination of joint fluid is necessary to exclude a septic process. Local injection into a previously infected joint is to be avoided.

Increase in pain and local swelling, further estriction of joint motion, fever and malaise are suggestive of septic arthritis.

If sepsis is confirmed, appropriate antimicrobial therapy should be instituted.

Corticosteroids should not be injected into unstable joints, infected areas or intervertebral spaces. Repeated injections into osteoarthritic

joints may increase joint destruction. Avoid injecting corticosteroids directly into tendons. Following intra-articular corticosteroid therapy,

care should be taken by the patient to avoid overuse of the joint in which symptomatic benefit has been obtained.

Pregnancy and lactation

Pregnancy category: C. Drug should not be used during pregnancy, if not necessary. As with all drugs, corticosteroids should

only be prescribed when the benefits to the mother and child outweigh the risks. Infants born of mothers who have received substantial doses

of corticosteroids during pregnancy should be carefully observed for signs of hypoadrenalism. When mothers were given betamethasone

injections prenatally, the infants had transient suppression of foetal growth hormone and presumably of those pituitary hormones which regulate

corticosteroid production by both the definitive and fetal zones of the fetal adrenal glands. However, the suppression of fetal hydrocortisone did

not interfere with the pituitary-adrenocortical responses to stress after birth.

Since transplacental passage of corticosteroids occurs, newborn and young infants born of mothers who were dosed with corticosteroids throughout
most or some portion of their pregnancy should be examined carefully for the possible very rare occurrence of congenital cataracts.

Overdose:

Treat metabolic effects of corticosteroid, main disease or concomitant disease or complications produced as a result of drug interactions.

In case of an acute overdose, maintain adequate fluid intake and monitor electrolytes in serum and urine, with particular attention to sodium
and potassium balance. Treat electrolyte imbalance if necessary.