

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PR **CELESTONE® SOLUSPAN®**

betamethasone sodium phosphate and betamethasone acetate injectable suspension

Read this carefully before you start taking **CELESTONE® SOLUSPAN®** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **CELESTONE® SOLUSPAN®**.

What is CELESTONE® SOLUSPAN® used for?

- For injection directly into the muscle: in allergic, skin, joint, muscle, bone and other conditions that respond to steroids. This also includes bursitis (swelling of the bursa, which are fluid filled sacs near joints).
- For injection directly into the affected tissues: in bursitis and other disorders causing swelling of tendons such as tenosynovitis and swelling of muscle such as fibrosis and myositis.
- For injection into or around joints: in rheumatoid arthritis and osteoarthritis.
- For injection into lesions: in various skin conditions.
- For local injection: in certain swelling and cystic disorders of the foot.

How does CELESTONE® SOLUSPAN® work?

CELESTONE® SOLUSPAN® contains steroid medication called betamethasone. It is used for the treatment of disorders that respond to steroid medications. This medication works to reduce swelling and allergic symptoms in skin, muscles, and joint.

What are the ingredients in CELESTONE® SOLUSPAN®?

Medicinal ingredients: betamethasone acetate and betamethasone (as betamethasone sodium phosphate).

Non-medicinal ingredients: benzalkonium chloride, disodium edetate, sodium phosphate dibasic dihydrate, sodium phosphate monobasic dihydrate, nitrogen and water for injection.

CELESTONE® SOLUSPAN® comes in the following dosage forms:

Injectable suspension: 3 mg betamethasone acetate and 3 mg betamethasone (as betamethasone sodium phosphate)/mL

Do not use CELESTONE® SOLUSPAN® if:

- you are allergic to betamethasone sodium phosphate and betamethasone acetate or any other corticosteroid medicine or any of the ingredients found in **CELESTONE® SOLUSPAN®** (see What are the ingredients in **CELESTONE® SOLUSPAN®**?).
- you have herpes simplex of the eye (a type of viral infection of the eye).
- you have a fungal infection or any untreated infection.
- you have vaccinia virus.
- you have malaria that has affected the brain.

- you have a decreased number of platelets when the medication is administered in the muscle.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take CELESTONE® SOLUSPAN®. Talk about any health conditions or problems you may have, including if you:

- have or have had an infection (such as a viral, bacterial or fungal infection).
- have a weak immune response. Tell your healthcare professional if you suspect an infection has occurred as corticosteroids can make infections more likely and may mask their signs.
- have recently had or are about to have any vaccination.
- have thyroid problems.
- have liver problems, such as cirrhosis
- have certain eye diseases such as glaucoma, cataracts, herpes infection or any problems with the retina.
- have stomach or gut problems.
- have kidney problems.
- have heart problems (such as heart failure, heart disease or heart attack) or blood pressure problems
- have a history of psychiatric problems or certain mental or mood conditions (such as depression).
- have or are suspected to have pheochromocytoma (tumor developing in an adrenal gland)
- have or are at an increased risk of brittle bone (osteoporosis)
- have a history of allergic reactions to corticosteroids
- have neurologic problems such as myasthenia gravis (neuromuscular disease leading to weakness of muscles).
- if you are breastfeeding or planning to breastfeed
- are pregnant or planning to become pregnant

Other warnings you should know about:

Nervous System:

Serious side effects with your nervous system, some resulting in death, have been reported with injection of corticosteroids into the back around the spinal cord (epidural injection).

These include but are not limited to:

- blockage of blood to the spinal cord
- paralysis of the lower body
- paralysis from the neck down
- blindness due to injury to a part of the brain
- stroke

The safety and effectiveness of corticosteroids in epidural injections is not known and should not be used.

Pregnancy and breastfeeding:

- If you are pregnant, or still able to get pregnant and/or breast-feed, there are specific risks you must discuss with your healthcare professional. Taking CELESTONE® SOLUSPAN® may:
 - slow the growth and cause low birth weight of the baby.

- cause cataracts in babies. This risk is associated with mothers who take corticosteroids for a long period of time during pregnancy.
- If you are breastfeeding or planning to breastfeed, tell your healthcare professional.

Male fertility:

- Taking CELESTONE® SOLUSPAN® may affect male fertility.

Immunosuppression:

- CELESTONE® SOLUSPAN® may:
 - hide symptoms of infection
 - reactivate dormant infections
 - cause infections due to lowered body resistance
- Tell your healthcare professional you are taking CELESTONE® SOLUSPAN® since it can affect the results of skin tests

Patients, especially children, should avoid exposure to chickenpox or measles while taking CELESTONE® SOLUSPAN®.

Contact your doctor if you experience blurred vision or other visual disturbances.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with CELESTONE® SOLUSPAN®:

- Medications that induce liver enzymes (e.g., barbiturates, phenytoin, carbamazepine, rifampin)
- Estrogens, including oral contraceptives
- Amphotericin B injection (used to treat fungal infections) and potassium-depleting agents
- Oral blood thinners
- Nonsteroidal anti-inflammatory agents (NSAIDs) (used to treat inflammation)
- Medicines for diabetes
- Somatotropin (medicine used to treat conditions of low growth hormone levels)
- Aminoglutethimide (medicine used to treat conditions where the body makes too much of a certain hormone)
- Antibiotics (medicines used to treat bacterial infections)
- Anticholinesterases (medicine used to prevent the breakdown of the neurotransmitter acetylcholine in the body)
- medicines for tuberculosis
- Cholestyramine (medicine used to lower cholesterol levels)
- Cyclosporine (medicine used to lower the risk of organ transplant rejection)
- Strong CYP3A4 Inhibitors
- Vaccines
- Alcohol

How to take CELESTONE® SOLUSPAN®:

- CELESTONE® SOLUSPAN® will be given to you by a healthcare professional in a healthcare setting.

Usual dose:

CELESTONE® SOLUSPAN® is a suspension for injection. The injection is usually administered by your doctor or a healthcare professional. Your doctor will determine the dose depending on your individual needs. Make sure you follow the dose prescribed by your doctor.

CELESTONE® SOLUSPAN® is for injection directly into the muscle, the affected tissues, into or around joints, into lesion and for local injection.

CELESTONE® SOLUSPAN® cannot be used for administration into the spinal canal.

Your doctor will evaluate your health regularly to make sure you get the correct dose.

Overdose:

Overdose may occur if you receive too much medication at one time or over a longer period of time. In case of accidental overdosage of CELESTONE® SOLUSPAN®, contact your doctor or local poison control centre to receive appropriate treatment.

If you think you, or a person you are caring for, have taken too much CELESTONE® SOLUSPAN®, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

If a dose of this medication has been missed, it should be taken as soon as possible. However, if it is almost time for the next dose, skip the missed dose and go back to the regular dosing schedule. Do not double doses.

What are possible side effects from using CELESTONE® SOLUSPAN®?

These are not all the possible side effects you may have when taking CELESTONE® SOLUSPAN®. If you experience any side effects not listed here, tell your healthcare professional.

Side effects may include:

- Skin problems:
 - facial redness
 - increased sweating
 - Petechiae (reddish spot containing blood that appears in the skin) and ecchymoses (bruises caused by ruptured blood vessels)
 - skin reactions such as:
 - allergic skin reactions
 - hives
 - swelling of skin or mucus tissues
 - darkening or lightening of skin
 - loss of fat under the skin
 - thinning of the skin
 - suppressed reactions to skin tests
- Hormone and metabolism problems:
 - for patients with diabetes, needing more insulin to treat their condition
 - symptoms of too much cortisol hormone, including but not limited to:
 - moon face (rounded puffy face)
 - weight gain

- abnormal fat deposits
 - not enough cortisol made by the body, particularly in times of stress (such as in trauma, surgery or illness)
 - suppression of growth in children
- Fluid and electrolyte problems:
 - sodium retention
 - potassium loss and experiencing symptoms caused by low potassium
- Stomach and gut problems:
 - bloating
 - hiccups
 - swelling of the pancreas
 - formation of ulcers on and swelling of the esophagus
- General disorders and administration problems:
 - increased pain at the injection site following the injection in the joint
 - abscess (a pus filled wound) with no infection
- Immune system problems:
 - decrease in blood pressure or shock like reactions
- Muscle and bone problems:
 - worsening of muscle weakness symptoms in myasthenia gravis
 - loss of bone near the shoulder and hip that is not caused by infection
 - joint instability (from repeated injections into a joint), loss of feeling in the foot and ankle
 - loss of muscle mass
 - partial or complete tear of tendon
 - vertebral compression fractures
- Nervous system problems:
 - headache
 - increased pressure in the skull with swelling of the nerve in the eye (pseudotumor cerebri) usually after treatment
 - dizziness
 - vertigo
- Eye problems:
 - cataracts
 - glaucoma (a condition that damages the optic nerve of the eye)
- Psychiatric problems:
 - euphoria (intense feelings of well-being, elation, happiness, excitement and joy)
 - mood swings
 - severe depression to psychotic manifestations (hallucinations, delusions, confused or disturbed thoughts)
 - personality changes
 - hyperirritability (extremely sensitive)
 - difficulty sleeping

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
Kaposi's Sarcoma (a type of cancer caused by human herpes virus 8): symptoms may include purple, red or brown blotches or tumours, usually on the skin of the legs, face or in the genital area		√	
Pheochromocytoma (tumor of the adrenal gland): symptoms may include high blood pressure, headache, heavy sweating, rapid heartbeat, tremors, paleness in the face, shortness of breath, panic attack-type symptoms			√
Neurologic events: blockage of blood to the spinal cord, paralysis of the lower body, paralysis from the neck down, blindness due to injury to a part of the brain, and stroke			√
Heart failure: shortness of breath, fatigue, weakness, dizziness, irregular heart beat			√
Blood clots: swelling, pain or tenderness, usually in the arm or leg		√	
Pancreatitis (inflammation of the pancreas): upper abdominal pain, fever, rapid heart beat, nausea, vomiting, tenderness when touching the abdomen		√	
Fluid retention, swelling		√	
High blood pressure: headaches or feeling unwell			√
Muscle weakness			√
Stomach ulcers (burst or bleeding ulcers): stomach pain, blood in stools and/or vomiting blood			√
Wounds that are slow to heal	√		
Convulsions			√

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
Psychological disorders: feeling depressed including thinking about suicide, feeling anxious, insomnia		√	
Irregular menstrual periods	√		
Diabetes: frequent urination, hunger and thirst		√	
Visual problems: failing eyesight, blurry vision, eye pain, increased pressure in your eyes		√	
Reactivation of tuberculosis: coughing blood or pain in the chest)			√
Infections: raised temperature and feeling unwell.			√
Osteoporosis (thin, fragile bones): bone/joint pain, broken bones, back pain that gets worse when standing or walking			√
Allergic reactions: rash, hives, swelling of the face, lips, tongue or throat. Difficulty swallowing or breathing			√

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

Store at 25°C, excursions permitted between 2 and 30°C. Protect from light.

Keep out of reach and sight of children.

If you want more information about CELESTONE® SOLUSPAN®:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: <https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>; the manufacturer's website www.organon.ca, or by calling 1-844-820-5468.

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