

# SPRIX® (ketorolac tromethamine) Nasal Spray

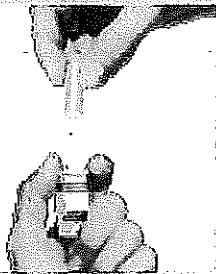
-effective pain relief

Please read these instructions  
before you use SPRIX.



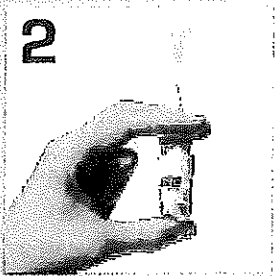
## Instructions for the use of SPRIX Nasal Spray

1



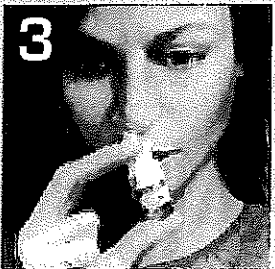
Before using SPRIX, remove the clear plastic cover and blue safety clip. Keep the clear plastic cover for future use. Remove and throw away the blue plastic safety clip.

2



Before using the bottle for the first time, you must activate the pump. To activate a new bottle, hold it at arm's length away from you and pump it 5 times by pressing and releasing the top lip of the bottle. You may not see a spray the first few times you press down. After activation, the bottle is ready to use. Each bottle of SPRIX contains 8 sprays for 24 hours of medication. There is no need to activate the pump again if more doses are used from the same bottle.

3

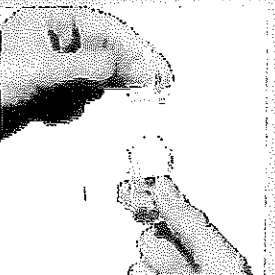


Blow your nose gently to clear your nostrils. With your head tilted slightly forward, insert the tip of the nozzle into your nostril. Point the tip toward the outside of the nostril, away from the center of the nose. Hold your breath, and press down evenly on the pump to deliver 1 spray into the nostril.

**SPRIX is for use in your nose only. Do not breathe in (inhale) SPRIX.**

Immediately after administration, pinch your nose and resume breathing through your mouth to help prevent the product from dripping. If your doctor has prescribed 1 spray in each nostril (2 sprays in total), repeat Step 3 in the other nostril.

### NOTES



- If the top portion of the bottle is pulled off the glass vial, reinsert it by lining up the nozzle carefully and softly pushing it back into the correct position. There is no need to reactivate the bottle.
- It is not necessary to put the bottle back in the refrigerator once it has been activated. Store upright in a cool, dry location out of direct sunlight. Keep out of reach of children.
- Do not use a bottle of SPRIX for more than 8 sprays or for more than 24 hours after activation.
- Throw away each SPRIX bottle within 24 hours of taking your first dose, even if the bottle still contains unused medicine.

### About SPRIX

Your healthcare provider has prescribed SPRIX (ketorolac tromethamine) Nasal Spray, a non-opioid pain reliever to treat moderate to moderately severe pain. It is important that you use SPRIX only as prescribed by your healthcare provider.

SPRIX has been shown to provide effective pain relief.

Each bottle of SPRIX contains 8 sprays, for 24 hours of medication.

- For adults 18 to 64 years of age, the recommended dose is 1 spray in each nostril every 6-8 hours.
- For adults with kidney problems, weighing less than 110 lbs, or 65 years of age or older, the recommended dose is 1 spray in only one nostril every 6-8 hours or as prescribed by your healthcare provider.

SPRIX is an NSAID (nonsteroidal anti-inflammatory drug), the same class of drugs as ibuprofen and aspirin.

SPRIX can help you manage short-term moderate to moderately severe pain for up to 5 days. Do not use SPRIX for more than 5 days in a row. If you still have pain after 5 days, contact your healthcare provider.

SPRIX should not be taken with aspirin or other NSAIDs.

SPRIX may interact with other medicines. Keep a list of your medicines to share with your healthcare provider and pharmacist.

Some patients may experience discomfort or irritation in the nose when using SPRIX. Generally, this lasts only a few minutes.

Some patients may experience irritation of the throat.

It is important that you drink plenty of fluids while you are using SPRIX.

SPRIX may be used by patients who are also using the nasal allergy medications fluticasone and oxymetazoline.

Do not use SPRIX more frequently than once every 6 hours, and use only at the prescribed amount.

SPRIX is preservative-free. Refrigerate bottles before use. After first use, keep the bottle at room temperature and throw away after 24 hours, even if the bottle still contains unused medicine.

Get emergency help right away if you have any of the following symptoms: shortness of breath or trouble breathing, chest pain, weakness in one part or side of your body, slurred speech, or swelling of the face or throat.

Stop using SPRIX and call your healthcare provider right away if you have any of the following symptoms: nausea, feeling more tired or weaker than usual, itching, your skin or eyes look yellow, stomach pain, flu-like symptoms, vomiting blood, there is blood in your bowel movement or it is black and sticky like tar, unusual weight gain, skin rash or blisters with fever, or swelling of the arms, legs, hands, or feet.

These are not all the side effects associated with SPRIX. Talk to your healthcare provider or pharmacist for more information about SPRIX.

Please see Important Safety Information on reverse, and accompanying complete Prescribing Information, including Boxed Warning and Medication Guide.



## What Is the Most Important Information I Should Know About SPRIX?

- SPRIX (ketorolac tromethamine), a nonsteroidal anti-inflammatory drug (NSAID), is indicated for the short term (up to 5 days in adults) management of moderate to moderately severe pain that requires analgesia at the opioid level. **Do not use SPRIX (ketorolac tromethamine) Nasal Spray alone, before, or after other forms of ketorolac for more than 5 days in a row.**

SPRIX should not be used if you are under 18 years of age or for minor or long-term painful conditions.

- **Gastrointestinal Risk:** SPRIX can cause serious ulcers and bleeding in the stomach or intestines at any time during treatment, which can happen without warning symptoms and may cause death. **Do not use SPRIX** if you have or have a history of peptic ulcer disease or stomach or intestinal bleeding or perforation. Elderly patients are at a greater risk for ulcers or bleeding in the stomach or intestines.
- **Bleeding Risk:** SPRIX reduces the ability of blood to clot and should not be used if you have or may have bleeding in the brain, a tendency to bleed, a decreased ability for blood to clot, or a high risk of bleeding.
- **Cardiovascular Risk:** SPRIX may increase the chance of a heart attack or stroke that can lead to death. This risk may increase if you take NSAIDs for long periods or if you have heart disease or risk factors for heart disease. **SPRIX should never be used** right before or after a heart bypass surgery.
- **Kidney Risk:** **SPRIX should not be used** if you have significantly reduced kidney function or if you are at risk for kidney failure due to low fluid levels (volume depletion).

### Do not take SPRIX:

- if you've had asthma, or other allergic-type reactions to aspirin, ketorolac, other NSAIDs or ethylenediaminetetraacetic acid (EDTA),
- if you have active ulcer disease or any history of bleeding in the stomach or intestines,
- before any major surgery or for pain right before, or after heart bypass surgery,
- if you have advanced kidney disease,
- for pain relief during labor and delivery,
- if you have had bleeding in the brain, a tendency to bleed, or have decreased ability for your blood to clot,
- with probenecid or pentoxifylline.

### Tell your healthcare provider:

- about all of your medical conditions and all of the medicines you take. SPRIX and some other medicines can interact with each other and cause serious side effects.
- if you are pregnant. **SPRIX should not be used by women late in their pregnancy.**
- if you are breastfeeding. Some SPRIX can pass into your breast milk.

**Serious side effects of SPRIX may include:** heart attack, stroke, high blood pressure, heart failure from body swelling (fluid retention), kidney problems including kidney failure, bleeding and ulcers in the stomach and intestine, low red blood cells (anemia), life-threatening skin reactions, life-threatening allergic reactions, liver problems including liver failure, and asthma attacks in people who have asthma.

**Get emergency help right away if you have the following symptoms:** shortness of breath or trouble breathing, chest pain, weakness in one part or side of your body, slurred speech, or swelling of the face or throat.

**Stop SPRIX and call your healthcare provider right away if you have any of the following symptoms:** nausea, more tired or weaker than usual, itching, your skin or eyes look yellow, stomach pain, flu-like symptoms, vomiting blood, there is blood in your bowel movement or it is black and sticky like tar, unusual weight gain, skin rash or blisters with fever, or swelling of the arms, legs, hands, or feet.

SPRIX can reduce the ability of the body to show signs of infection (fever and inflammation).

Keep SPRIX away from your eyes. If you get SPRIX in your eyes, wash out the eye with water or saline, and call a doctor if irritation persists for more than an hour.

**The most common side effects of SPRIX are:** discomfort in the nose, nose pain, increased tear production, throat irritation, low urine output, rash, slow heart rate, increased liver enzymes, high blood pressure, and stuffy nose.

**For more information please see accompanying complete Prescribing Information, including Boxed Warning and Medication Guide.**

**You are encouraged to report negative side effects of prescription drugs to the FDA. Visit [www.fda.gov/medwatch](http://www.fda.gov/medwatch) or call 1-800-FDA-1088.**

**For SPRIX product information or to report a side effect call 1-800-518-1084.**

For SPRIX customer service or questions about product availability visit [www.SPRIX.com](http://www.SPRIX.com), or call 1-844-97-SPRIX (1-844-977-7749).

For a video showing how to use SPRIX, scan here.

