SPRIX®
(ketorolac tromethamine)
Nasal Spray
15.75 mg per spray

SPRIX® (ketorolac tromethamine) is used in adult patients for the short term (up to 5 days) management of moderate to moderately severe pain that requires analgesia at the opioid level.

A NON-OPIOID OPTION FOR SHORT-TERM PAIN RELIEF

NOT

AN OPIOID
A NARCOTIC
A CONTROLLED SUBSTANCE

IMPORTANT SAFETY INFORMATION ABOUT SPRIX®

What is the most important information I should know about SPRIX and prescription Nonsteroidal Anti-inflammatory Drugs (NSAIDs)?

Sprix (ketorolac tromethamine) Nasal Spray is an NSAID.

NSAIDs can cause serious side effects including, increased risk of a heart attack or stroke that can lead to death. This risk may happen early in treatment and may increase with increasing doses of NSAIDs and with longer use of NSAIDs.

NSAIDs can also cause increased risk of bleeding, ulcers, and tears (perforation) of the esophagus (tube leading from the mouth to the stomach), stomach and intestines which may occur anytime during use, without warning symptoms, and may cause death.

See the **Boxed Warning: Risk of Serious Cardiovascular and Gastrointestinal Events**

Do not take SPRIX right before or after a heart surgery called a "coronary artery bypass graft (CABG)."

Do not take SPRIX after a recent heart attack, unless your healthcare provider tells you to. You may have an increased risk of another heart attack if you take NSAIDs after a recent heart attack.

Please see additional Important Safety Information on the next pages.

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WHY CHOOSE SPRIX

SPRIX® (ketorolac tromethamine) Nasal Spray, approved in 2010, is the first prescription NSAID nasal spray that contains the potent pain reliever ketorolac.

SPRIX IS:

Prescribed for adult patients with moderate to severe pain who require opioid-strength pain relief for up to 5 days.

The first nonsteroidal anti-inflammatory drug (NSAID) pain-relieving nasal spray

A medicine that contains a **potent pain reliever**

Delivered right to your door

SPRIX IS

NOT AN OPIOID
NOT A NARCOTIC
NOT A CONTROLLED SUBSTANCE

ASK YOUR HEALTHCARE PROVIDER IF SPRIX NASAL SPRAY IS RIGHT FOR YOU.

IMPORTANT SAFETY INFORMATION ABOUT SPRIX® (Continued)

The risk of getting an ulcer or bleeding also increases with:

- Taking medicines called "corticosteroids", "anticoagulants", "SSRIs", or "SNRIs"
- Increasing doses of NSAIDs
- Longer use of NSAIDs
- Smoking
- Drinking alcohol
- Poor health
- Advanced liver disease
- Bleeding problems

SPRIX should only be used:

- Exactly as prescribed
- At the lowest dose possible for your treatment
- For the shortest time needed

What is SPRIX®?

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Limitations of Use

- Sprix is not for use in pediatric patients less than 2 years of age.

Do not use SPRIX®:

- If you are allergic to ketorolac or any components of the drug product
- If you have had an asthma attack, hives, or other allergic reaction with aspirin or any other NSAIDs
- Right before or after heart bypass surgery
- If you have active ulcer disease or any history of bleeding in the stomach or intestines
- If you have had bleeding in the brain, a tendency to bleed, or have decreased ability for your blood to clot
- If you have kidney disease
- If you are taking probenecid or pentoxifylline
- For more than 5 days or with other formulations of ketorolac or with other NSAIDs

Before taking SPRIX or any NSAID, tell your healthcare provider about all of your medical conditions, including if you:

- have liver or kidney problems
- have high blood pressure or heart failure
- have asthma
- have bleeding problems
- are pregnant or plan to become pregnant. Taking NSAIDs, including SPRIX at about 20 weeks of pregnancy or later may harm your unborn baby. If you need to take NSAIDs for more than 2 days when you are between 20 and 30 weeks of pregnancy, your healthcare provider may need to monitor the amount of fluid in your womb around your baby. **You should NOT take SPRIX, after about 30 weeks of pregnancy.**
- are breastfeeding or plan to breast feed. Some SPRIX can pass into your breast milk.

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EACH CARTON CONTAINS **5 BOTTLES**

Use SPRIX exactly as your healthcare provider tells you to use it. The approved/recommended use is:

- Every 6-8 hours*
- Up to 4 times a day
- For up to 5 days

*For adult patients <65 years of age, ≥110 lbs, and with normal kidney function, the recommended dose is 1 spray in each nostril every 6-8 hours, up to 4 times a day. For adult patients ≥65 years of age, renally impaired patients, and adult patients <110 lbs, the recommended dose is 1 spray in 1 nostril every 6-8 hours, up to 4 times per day.

HOW SHOULD I **STORE SPRIX?**

Refrigerate unopened SPRIX bottles between 36°F to 46°F (2°C to 8°C)

Keep opened bottles of SPRIX at room temperature, 59°F to 86°F (15°C to 30°C)

SPRIX does not contain a preservative. Throw away each SPRIX bottle within 24 hours of taking your first dose, even if the bottle still contains some liquid.

Keep SPRIX out of direct sunlight

Do not freeze SPRIX

INSTRUCTIONS FOR USE OF **SPRIX® NASAL SPRAY**

SPRIX is for use in the nose only. Do not breathe in (inhale) SPRIX. Use SPRIX exactly as your healthcare provider tells you to use it. Do not use SPRIX for more than 5 days. If you still have pain after 5 days, contact your healthcare provider. Do not use SPRIX more than every 6 hours. It is important that you drink plenty of fluids while you are using SPRIX. Tell your healthcare provider if you urinate less while using SPRIX. You may have discomfort or irritation in your nose when using SPRIX. This usually lasts for a short time.

1

Figure A

PREPARE

Before you use SPRIX for the first time, you will need to prime the bottle. Hold the finger flange with your fingers (see Figure A), and remove the clear plastic cover with your opposite hand. Keep the clear plastic cover for later. Remove and throw away the blue plastic safety clip.

2

Figure B

POSITION

If the clear plastic cover is improperly removed, the tip of the bottle may be pulled off of the glass vial. If this happens, place the tip back onto the glass vial by lining it up carefully and gently pushing it back on until it is back in the correct position (see Figure B). The SPRIX bottle should work properly again.

3

Figure C

PRIME

Hold the SPRIX bottle upright, at arm's length away from you, with your index finger on top of the finger flange and your thumb supporting the base (see Figure C). Press down on the finger flange and release the pump 5 times. You may not see spray the first few times you press down. Now the pump is primed and ready to use. You do not need to prime the pump again if you use more doses from this bottle.

4

Figure D

PUMP

Blow your nose to clear your nostrils. Sit up straight or stand. Keep your head tilted downward toward your toes. Place the tip of the SPRIX bottle into your right nostril. Hold the SPRIX bottle upright and aim the tip away from the center of your nose (see Figure D).

Hold your breath and spray 1 time into your right nostril, pressing down on both sides of the finger flange (see Figure D). Breathe in gently through your mouth after you use SPRIX. You may also pinch your nose to help keep the medicine in your nose.

If your healthcare provider has prescribed only 1 spray per dose for you, you have now finished your dose. However, if your healthcare provider has prescribed 2 sprays for you, repeat the above steps for your left nostril. Be sure to point the spray away from the center of your nose. Spray 1 time into your left nostril. When you are finished using SPRIX, put the clear plastic cover back on the SPRIX bottle.

Visit sprix.com to watch the Instructions for Use video.

IMPORTANT SAFETY INFORMATION ABOUT SPRIX® (Continued)

Tell your healthcare provider about all of the medicines you take, including prescription or over-the-counter medicines, vitamins or herbal supplements. SPRIX and some other medicines can interact with each other and cause serious side effects. Do not start taking any new medicine without talking to your healthcare provider first.

What are the possible side effects of SPRIX?

See "What is the most important information I should know about SPRIX and prescription Nonsteroidal Anti-inflammatory Drugs (NSAIDs)?"

- new or worse high blood pressure
- heart failure
- liver problems including liver failure
- kidney problems including kidney failure
- low red blood cells (anemia)
- life-threatening skin reactions

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- kidney problems including kidney failure
- low red blood cells (anemia)
- life-threatening skin reactions
- life-threatening allergic reactions

Other side effects of NSAIDs include: stomach pain, constipation, diarrhea, gas, heartburn, nausea, vomiting, and dizziness.

Most common side effects with SPRIX include: discomfort in the nose; pain in the nose; increased tears; throat irritation; decreased amount of urine; rash; slow heart rate; increased liver enzymes; high blood pressure; stuffy nose.

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.

Get emergency help right away if you get any of the following symptoms:

- shortness of breath or trouble breathing
- chest pain
- weakness in one part or side of your body
- slurred speech
- swelling of the face or throat

Stop taking SPRIX and call your healthcare provider right away if you get any of the following symptoms:

- nausea
- more tired or weaker than usual
- diarrhea
- itching
- your skin or eyes look yellow
- indigestion or stomach pain
- flu-like symptoms
- vomit blood
- there is blood in your bowel movement or it is black and sticky like tar
- unusual weight gain
- any type of rash or fever
- swelling of the arms, legs, hands, and feet

If you take too much SPRIX, call your healthcare provider or get medical help right away.

These are not all the possible side effects of NSAIDs. For more information, ask your healthcare provider or pharmacist about NSAIDs.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

Please see full Prescribing Information, including **Boxed Warning** and patient **Medication Guide,** at www.sprix.com/PI.

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AVAILABLE THROUGH THE SPRIX DIRECT PHARMACY AND DELIVERED TO YOUR HOME

If you did not sign a prescription form, call us today to ensure that you receive your medication as quickly as possible.

1-844-97-SPRIX
(1-844-977-7749)

Sign the prescription form with your doctor

$0 Co-pay for patients with eligible commercial insurance*

SPRIX is delivered to your home

Take SPRIX as directed
Do not breathe in (inhale) SPRIX

*Contact Sprix Direct for full terms and conditions.

Please see Important Safety Information on pages 6 and 7 and the enclosed Medication Guide and the full Prescribing Information including Boxed Warning.

Zyla life sciences

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