

APOKYN® Pen Instructions for Use

Designed to be used only with

3 mL APOKYN® (apomorphine hydrochloride injection) Cartridges

For more information, call your specialty pharmacy provider or 1-877-7APOKYN (727-6596).

**APOKYN®
(apomorphine hydrochloride injection)**



APOKYN Pen

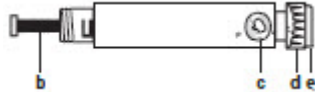
- **APOKYN[®] (apomorphine hydrochloride injection) is for under the skin (subcutaneous) injection only.**
- **Do not** inject APOKYN into a vein.
- **Do not** use the APOKYN[®] Pen unless you and your care partner have been taught the right way to use it and both of you understand all of the instructions.
- The **APOKYN Pen** is for use only with 3 mL **APOKYN[®] (apomorphine hydrochloride injection) Cartridges.**
- The **APOKYN Pen** is only for use by 1 patient and should not be shared.

Gray Pen Cap



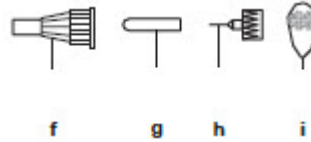
a. Clip

Gray Pen Body



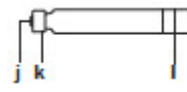
b. Black Rod
c. White Dose Window
d. White Dose Knob
e. Teal Injection Button

Pen Needle Unit



f. Outer Needle Shield
g. Pink Inner Needle Shield
h. Pen Needle
i. Pink Paper Tab

Cartridge



j. Rubber Septum
k. Metal Cap
l. Cartridge Plunger

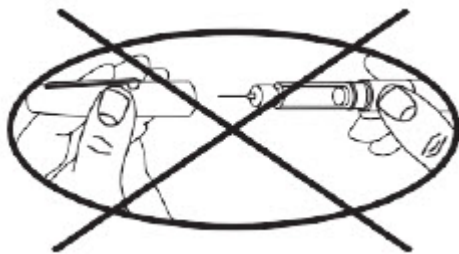
Teal Cartridge Holder



Read First: Important Safety Information

- ◆ The **APOKYN Pen** is a medicine delivery device. It is very important that you or your care partner read this Instructions for Use and follow the instructions for using the **APOKYN Pen** correctly to receive the correct APOKYN dose.
- ◆ Always perform a flow check (prime) before every injection and after loading a new cartridge.
- ◆ The liquid in the **APOKYN Cartridge** can cause irritation if it gets on your skin or in your eyes. Flush your eyes with cold water and wash the liquid off your skin right away if this happens.
- ◆ The BD pen needle unit is sterile. Avoid contaminating the needle after opening. **Do not** place it on a surface or touch other items with the needle.
- ◆ **Do not** dial the dose or try to correct a dialing error with the pen needle in the skin. You could receive the wrong dose.
- ◆ Be careful when removing the needle. Accidental needle sticks can transmit serious infections.

Never store or carry the APOKYN Pen with a pen needle attached.



Storing or carrying the **APOKYN Pen** with a pen needle attached may let:

- ◆ Air enter the cartridge
- ◆ Medicine leak out

This can affect your APOKYN dose.

Never recap pen with needle attached.

The **APOKYN Pen** should only be used with pen needles (29G × 1/2"). These needles are available through your specialty pharmacy provider or your local pharmacy.



New Needle

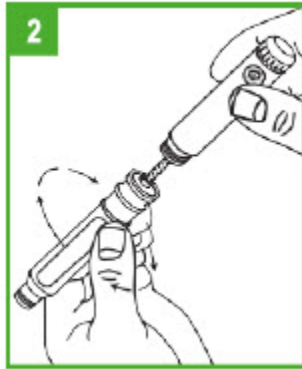
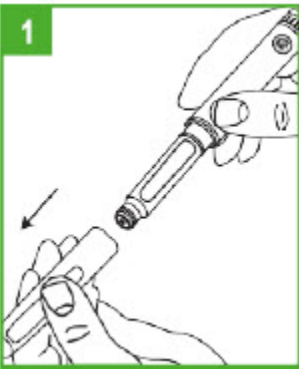
You must use a new, sterile BD pen needle with each injection.



Reused Needle

Magnification: 50×

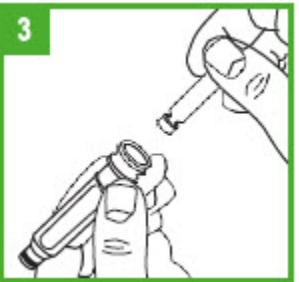
How to Use the APOKYN Pen



Preparing the APOKYN Pen for Cartridge Loading

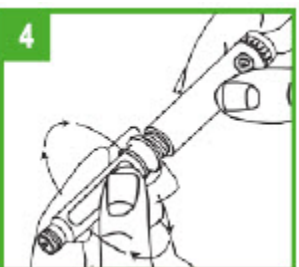
Step 1. Remove the gray pen cap by pulling it straight off.

Step 2. Unscrew the teal cartridge holder from the gray pen body by turning it clockwise.



Loading a Cartridge

Step 3. Only use **APOKYN** that is clear and colorless. Do not use an **APOKYN Cartridge** that contains medicine that is cloudy, green, or contains particles. Call your specialty pharmacy provider for replacement cartridges. Insert the **APOKYN Cartridge**, metal cap first, into the teal cartridge holder.



Step 4. Lower the gray pen body onto the teal cartridge holder so that the black rod presses against the cartridge plunger. Screw the teal cartridge holder onto the gray pen body. Tighten the pieces by turning the teal cartridge holder clockwise until no gap remains and 1 of the white arrows line up with the white marker on the gray pen body.

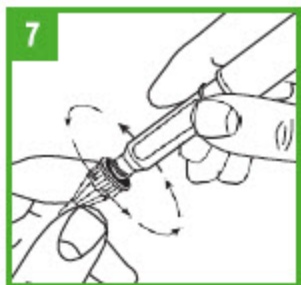


Step 5. If you already have a cartridge in the pen and have used the pen, you should check the cartridge through the window in the teal cartridge holder to make sure there is enough **APOKYN** solution in the cartridge to provide your next dose. If the gray cartridge plunger has reached the red line on the cartridge, remove the cartridge and insert a new cartridge into the pen before attaching the pen needle and preparing the dose.



Attaching the Pen Needle

Step 6. Remove the pink paper tab from the back of a new pen needle. Use a new needle for each injection. **Never reuse needles.**



Step 7. Holding the **APOKYN Pen** by the teal cartridge holder, push the pen needle unit onto the pen. Screw the threaded hub of the pen needle onto the teal cartridge holder counter-clockwise. When the needle unit is attached, remove the outer shield that protects the needle with a gentle pull. Save the outer shield. You will use it to remove the needle from the pen after the injection is finished. **Do not** remove the inner needle shield at this time. **The needle is sterile and must stay clean. After opening, do not place the needle on a surface or let it touch anything.**

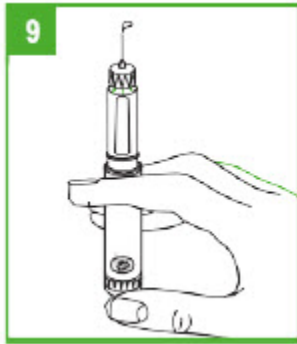
Preparing (Priming) the APOKYN Pen for Use

IMPORTANT – Prior to each injection, it is important that the **APOKYN Pen** be properly primed. **For a new APOKYN Cartridge** (1 that has **not** been used before), repeat the priming procedure described on the next page (Steps 8-9) 3 or 4 times to make sure all the air has been removed from the needle and cartridge.

For an APOKYN Cartridge you have used before (1 that has been previously primed), repeat the priming procedure described on the next page (Steps 8-9) **1 time** to make sure all the air has been removed from the needle and cartridge.

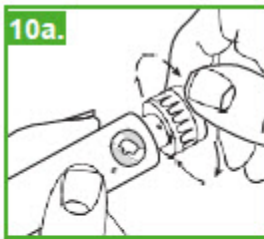


Step 8. You must prepare (prime) the **APOKYN Pen** for use before injecting the medicine. To prime the **APOKYN Pen**, set the dose by turning the dose knob to 0.1 mL. This is important so you can get rid of any air bubbles in the cartridge.



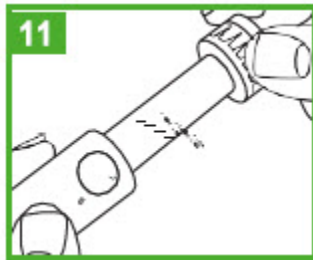
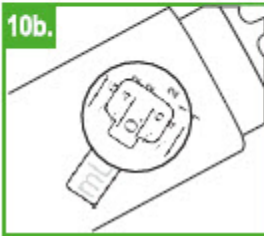
Step 9. Remove the inner needle shield. Remember, **do not** let the needle touch anything. With the needle pointing up, firmly push the injection button in as far as it will go and hold for at least 5 seconds. A small stream of medicine must come out of the end of the needle. If it does not, reset the dose by repeating Step 8. Repeat these steps (Steps 8-9) until a small stream of medicine comes out of the end of the needle. When medicine comes out of the end of the needle, the **APOKYN Pen** is primed for injection and ready to use.

APOKYN medicine can cause staining to fabric and other surfaces it touches. Be careful where you prime the **APOKYN Pen**.



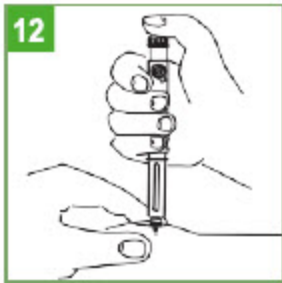
Setting the Dose

Step 10. To set the dose, turn the white dose knob until the correct dose (number of mLs) is shown in the window. The dose will appear as a red number between two black lines that will line up next to the letters "mL" on the pen body. Make sure the correct number (dose) appears in the window.



Step 11. Dose Correction. If you turn the dose knob past your dose, **do not** dial backwards. If you dial backwards, APOKYN will be pushed through the needle and you will lose medicine. Continue to turn the dial until it is fully turned. Press the injection button fully. This will reset the dial to zero without pushing medicine out of the needle. Repeat Step 10 to redial your dose.

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Giving the Injection

Step 12. APOKYN is only for injection under the skin (subcutaneous injection). Choose an injection site on your stomach area, upper arm or upper leg. Change the site with each injection. **Do not** inject APOKYN into skin that is red or sore.

Clean the site with an alcohol swab and allow to air dry. Pinch about an inch of skin and fat tissue of your injection site between your thumb and forefinger. With the other hand, insert the needle all the way into the pinched skin.

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Step 13. Fully push the teal injection button on the APOKYN Pen. A clicking sound will be heard while the dose is injected. Push the injection button firmly for 5 seconds. Remove the needle from your skin. If medicine keeps dripping from the needle, keep the needle in the skin longer the next time you inject APOKYN.

IMPORTANT – If you set your dose and cannot depress the teal injection button, the cartridge is empty. Remove the pen needle and cartridge and prepare the pen as described in Steps 2-9 with a new cartridge. Set the dose and give the injection.

If you set your dose and the injection button stops before you receive a complete dose, note the number in the window, remove the pen needle and cartridge, and prepare the pen as described in Steps 2-9 with a new cartridge. Set the dose to the number that last appeared in the window and administer the injection. This completes the dose.

Before attempting to replace a cartridge, be sure that a needle unit is not attached to the APOKYN Pen.

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Removing the Pen Needle

Step 14. Carefully replace the outer needle shield. Be careful to avoid a needle-stick. Place the outer needle shield in the notch located on the far left side of your carrying case. The opening of the needle shield should be pointing up. Carefully insert the needle (attached to the pen) into the opening of the shield. **Without holding onto the shield,** push down firmly.

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Step 15. Hold the pen by the teal cartridge holder and unscrew the pen needle from the cartridge holder. Recap the pen. **Never recap the pen with a needle attached.** Safely dispose of used pen needles in a "sharps" container. Your specialty pharmacy provider will provide you with a "sharps" container. **Do not throw used needles in a trash can.**

Storage Information

–Store APOKYN cartridges at room temperature, 68°F to 77°F (20°C to 25°C)

Excursions permitted between 59 to 86°F (15 to 30°C) [See USP Controlled Room Temperature]

Proper Disposal

- ◆ Put your used needles and syringes in an FDA-cleared sharps disposal container right away after use. Do not throw away (dispose of) loose needles and syringes in your household trash.

- ◆ If you do not have an FDA-cleared sharps disposal container, you may use a household container that is:
 - made of a heavy-duty plastic
 - able to be closed with a tight-fitting, puncture-resistant lid, without sharps being able to come out
 - upright and stable during use
 - leak-resistant
 - properly labeled to warn of hazardous waste inside the container
- ◆ When your sharps disposal container is almost full, you will need to follow your community guidelines for the right way to dispose of your sharps disposal container. There may be state or local laws about how you should throw away used needles and syringes. For more information about safe sharps disposal, and for specific information about sharps disposal in the state that you live in, go to the FDA's website at: <http://www.fda.gov/safesharpsdisposal>.
- ◆ Do not dispose of your used sharps disposal container in your household trash unless your community guidelines permit this. Do not recycle your used sharps disposal container.

Care and Storage

The APOKYN Pen can now be stored in its carrying case. **Never store or carry the APOKYN Pen with a pen needle attached.**

You must store and care for your pen the right way:

- ◆ Avoid exposure to dust, moisture, and cold or hot temperatures.
- ◆ Never wash the pen in water or use strong disinfectants. Only a clean, damp cloth should be used for cleaning.
- ◆ **Do not** try to repair the pen if it is damaged or if you cannot solve a problem shown in the following "Troubleshooting" section.
- ◆ **Do not** use pen for more than 1 year after the first use or after the expiration date on the carton.

For more information, call your specialty pharmacy provider or 1-877-7APOKYN (727-6596).

Troubleshooting

PROBLEM	POSSIBLE CAUSE	HOW TO FIX THE PROBLEM
No medicine comes out of the pen (the dosage dial moves freely, but no click is heard).	The pen is in dose correction mode.	Push the injection button all the way in so the dial returns to zero.
The dosage dial does not return to zero during an injection.	The cartridge is empty.	Replace the cartridge as described in Steps 3-5.
	The pen needle is clogged.	Replace the pen needle as described in Steps 14 & 6-7.
The dosage dial does not turn easily.	Dust or dirt is on the pen.	Turn the dial past the highest setting on the pen. Wipe all exposed pen surfaces with a clean, damp cloth.
Pen does not close.	Cartridge is inserted incorrectly.	Remove cartridge and reload it. See Steps 3-4.
Injection button will not depress.	Cartridge is empty.	Replace cartridge. See Steps 3-5.
Injection button stops before a complete dose is delivered.	Not enough medication in cartridge to complete the dose.	Replace cartridge. See Steps 3-5.

Pen does not work.	Mechanical failure.	Replace pen. Call your specialty pharmacy provider or 1-877-7APOKYN (727-6596).
Dose numbers and/or white markers wear off.	Repeated use over extended period of time.	Replace pen. Call your specialty pharmacy provider or 1-877-7APOKYN (727-6596).
Too much force needed to depress injection button.	Defective cartridge.	Replace cartridge. See Steps 3-5.
Unable to read the dose numbers through the dose window.	Incorrect cleaning or improper handling.	Replace pen. Call your specialty pharmacy provider or 1-877-7APOKYN (727-6596).

For more information, call your specialty pharmacy provider or 1-877-7APOKYN (727-6596).

Patient Information

APOKYN® (AY-po-kin) (apomorphine hydrochloride injection)

Read this Patient Information before you start using APOKYN and each time you get a refill. There may be new information. This information does not take the place of talking to your healthcare provider about your medical condition or your treatment.

What is APOKYN?

APOKYN is a prescription medicine used to treat acute, intermittent episodes of poor mobility called "off" episodes (end-of-dose wearing "off" or unpredictable "on-off" episodes) in people with advanced Parkinson's disease (PD).

It is not known if APOKYN is safe and effective in children.

Who should not take APOKYN?

Do not take APOKYN if you are:

- taking certain medicines to treat nausea called 5HT₃ antagonists including, ondansetron, granisetron, dolasetron, palonosetron, and alosetron. People taking ondansetron together with apomorphine, the active ingredient in APOKYN, have had very low blood pressure and lost consciousness or "blacked out."
- allergic to apomorphine hydrochloride or to any of the ingredients in APOKYN and experience hives, itching, rash, or swelling (e.g., eyes, tongue, etc.). APOKYN also contains a sulfite called sodium metabisulfite. Sulfites can cause severe, life-threatening allergic reactions in some people. An allergy to sulfites is not the same as an allergy to sulfa. People with asthma are more likely to be allergic to sulfites. Call your healthcare provider if you have hives, itching, rash, swelling of the eyes, tongue, lips, chest pain, trouble breathing or swallowing. See the end of this leaflet for a complete list of ingredients in APOKYN.

What should I tell my healthcare provider before taking APOKYN?

Before you start using APOKYN, tell your healthcare provider if you:

- have difficulty staying awake during the daytime
- have dizziness
- have fainting spells
- have low blood pressure
- have asthma

- are allergic to any medicines containing sulfites
- have liver problems
- have kidney problems
- have heart problems
- have had a stroke or other brain problems
- have a mental problem called a major psychotic disorder
- drink alcohol
- are pregnant or plan to become pregnant. It is not known if APOKYN will harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if APOKYN passes into your breast milk. You and your healthcare provider should decide if you will take APOKYN or breastfeed. You should not do both.

Tell your healthcare provider about all the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements.

Using APOKYN with certain other medicines may affect each other. Using APOKYN with other medicines can cause serious side effects.

- If you take nitroglycerin under your tongue while using APOKYN, your blood pressure may decrease and cause dizziness. After taking nitroglycerin, you should lie down and try to continue lying down for at least 45 minutes. You should avoid standing for 45 minutes after taking nitroglycerin.

Know the medicines you take. Keep a list of them to show your healthcare provider or pharmacist when you get a new medicine.

How should I use APOKYN?

- Read the Instructions for Use starting on page 6 of this leaflet for specific information about the right way to use APOKYN.
- Use APOKYN exactly as your healthcare provider tells you to use it.
- Your healthcare provider will tell you how much APOKYN to use and teach you the right way to use it.
- Your healthcare provider may change your dose if needed.
- **Do not** change your dose of APOKYN or use it more often than prescribed unless your healthcare provider has told you to.
- **Do not** give another dose of APOKYN sooner than 2 hours after the last dose.
- Your healthcare provider will prescribe APOKYN that comes in prefilled glass cartridges, for single-patient-use, that are used with a special pen injector.
- Your APOKYN pen is dosed in milliliters (mL), **not** milligrams (mg). Make sure your prescription tells you how many milliliters (mL) to use.
- Inject APOKYN under your skin (subcutaneously). **Do not** inject APOKYN into a vein.
- Keep a record of how much APOKYN you have used each time you inject or your care partner gives you an injection.
- Use a new needle with each injection. Never reuse a needle.
- APOKYN is a clear and colorless liquid. Do not use APOKYN if it appears cloudy, colored, or to contain particles, and call your pharmacist.
- Your healthcare provider may prescribe another medicine called an antiemetic to take while you are using APOKYN. Antiemetic medicines help to decrease the symptoms of nausea and vomiting that can happen with APOKYN.

- If you take too much APOKYN, call your healthcare provider. If you experience severe or serious side effects such as chest pain or prolonged erection lasting more than 4 hours, go to the nearest hospital emergency room.

What should I avoid while using APOKYN?

- **Do not** drink alcohol while you are using APOKYN. It can increase your chance of developing serious side effects.
- **Do not** take medicines that make you sleepy while you are using APOKYN.
- **Do not** drive, operate machinery, or do other dangerous activities until you know how APOKYN affects you.
- **Do not** change your body position too fast. Get up slowly from sitting or lying. APOKYN can lower your blood pressure and cause dizziness or fainting.

What are the possible side effects of APOKYN?

APOKYN may cause serious side effects. Call your healthcare provider right away if you have any of the serious side effects, including:

- **allergic reaction.** An allergic reaction with side effects of hives, itching, rash, swelling (e.g., eyes, tongue, etc.); trouble breathing and/or swallowing may occur after injecting APOKYN.
- **blood clots.** Injecting APOKYN into a vein (intravenous) can cause blood clots. **Do not** inject APOKYN in your vein.
- **nausea and vomiting.** Nausea and vomiting, which may be severe, can happen with APOKYN. Your healthcare provider may prescribe a medicine to help decrease nausea and vomiting. Follow your healthcare providers instructions on how to take and when to stop this medicine.
- **sleepiness or falling asleep during the day.** Some people treated with APOKYN may get sleepy during the day or fall asleep without warning while doing everyday activities such as talking, eating, or driving a car.
- **dizziness.** APOKYN can lower your blood pressure and cause dizziness. Dizziness can happen when APOKYN treatment is started or when the APOKYN dose is increased. **Do not** get up too fast from sitting or after lying down, especially if you have been sitting or lying down for a long period of time.
- **falls.** The changes that can happen with Parkinson's disease (PD), and the effects of some PD medicines, can increase the risk of falling. APOKYN may also increase your risk of falling.
- **hallucinations or psychotic-like behavior.** APOKYN can cause or worsen psychotic-like behavior including hallucinations (seeing or hearing things that are not real), confusion, excessive suspicion, aggressive behavior, agitation, delusional beliefs (believing things that are not real), and disorganized thinking.
- **sudden uncontrolled movements (dyskinesias).** Some people with PD may get sudden, uncontrolled movements after treatment with some PD medicines. APOKYN can cause or make dyskinesias worse.
- **low red blood cells (hemolytic anemia).** Tell your healthcare provider if you have any of the following signs or symptoms: you become pale, fast heartbeat, feel more tired or weaker than usual, skin or eyes look yellow, chest pain, shortness of breath or trouble breathing, dark-colored urine, fever, dizziness, or confusion.
- **intense urges.** Some people with PD have reported new or increased gambling urges, increased sexual urges, and other intense urges, while taking PD medicines, including APOKYN.
- **heart problems.** If you have shortness of breath, fast heartbeat, or chest pain while taking APOKYN, call your healthcare provider or get emergency help right away.
- **serious heart rhythm changes (QT prolongation).** Tell your healthcare provider right away if you have a change in your heartbeat (a fast or irregular heartbeat), or if you faint.

- **injection site problems.** Bruising, swelling, and itching can happen at the site where you inject APOKYN.
- **fever and confusion.** This can happen in some people when their PD medicine is stopped or there is a fast decrease in the dose of their PD medicine.
- **tissue changes (fibrotic complications).** Some people have had changes in the tissues of their pelvis, lungs, and heart valves when taking medicines called nonergot derived dopamine agonists like APOKYN.
- **prolonged painful erections (priapism).** APOKYN may cause prolonged, painful erections in some people. If you have an erection that lasts more than 4 hours you should call your healthcare provider or go to the nearest hospital emergency room right away.
- **swelling of ankles/legs.** APOKYN may cause swelling, especially in the ankles or legs. Tell your healthcare provider if you notice any swelling.

Other common side effects of APOKYN include:

- yawning
- runny nose
- confusion
- swelling of your hands, arms, legs, and feet

Tell your healthcare provider if you have any side effect that bothers you or that does not go away.

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

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

You may also report side effects to MDD US Operations, LLC at 1-877-727-6596.

How should I store APOKYN?

- Store APOKYN at room temperature, 68°F to 77°F (20°C to 25°C).
- Safely throw away medicine that is out of date or no longer needed.

Keep APOKYN and all medicines out of the reach of children.

General information about the safe and effective use of APOKYN.

Medicines are sometimes prescribed for purposes other than those listed in a patient information leaflet. Do not use APOKYN for a condition for which it was not prescribed. Do not give APOKYN to other people, even if they have the same symptoms that you have. It may harm them.

This Patient Information leaflet summarizes the most important information about APOKYN. If you would like more information, talk with your healthcare provider. You can ask your pharmacist or healthcare provider for information about APOKYN that is written for health professionals.

For more information, go to www.apokyn.com or call 1-877-727-6596.

What are the ingredients in APOKYN?

Active ingredient: apomorphine hydrochloride, USP

Inactive ingredients: sodium metabisulfite, NF, benzyl alcohol, NF, water for injection, USP. It may also contain sodium hydroxide, NF and/or hydrochloric acid, NF.

This Patient Information and Instructions for Use has been approved by the U.S. Food and Drug Administration.

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1 Becton Drive
Franklin Lakes, NJ 07417, USA

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