PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

SINCALIDE FOR INJECTION

Sincalide for Injection

Read this carefully before you start taking **SINCALIDE FOR INJECTION** 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 **SINCALIDE FOR INJECTION**.

What is SINCALIDE FOR INJECTION used for?

- SINCALIDE FOR INJECTION causes contraction of the gall bladder which causes it to release bile. This can be used to help in the examination of the bile ducts; as well as for collection of bile to diagnose health problems.
- SINCALIDE FOR INJECTION can be used together with another product (Secretin-sincalide test) to collect fluid and cells from the pancreas. This can be used to test for cancer of the pancreas.
- SINCALIDE FOR INJECTION can be used to treat a lack of movement in the intestines
 that sometimes occurs after surgery. This lack of movement can sometimes lead to a
 buildup of food which can block the intestines.
- SINCALIDE FOR INJECTION can be used to increase contractions in the intestines. This speeds up the movement of dyes used for diagnostic imaging.

How does SINCALIDE FOR INJECTION work?

SINCALIDE FOR INJECTION works by making the smooth (involuntary) muscles in the gastrointestinal tract contract.

What are the ingredients in SINCALIDE FOR INJECTION?

Medicinal ingredient: Sincalide

Non-medicinal ingredients: Arginine hydrochloride, hydrochloric acid (and/or sodium hydroxide), lysine monohydrochloride, mannitol, methionine, pentetic acid, sodium metabisulfite

SINCALIDE FOR INJECTION comes in the following dosage forms:

Powder for solution for injection, 5 mcg / vial

Do not use SINCALIDE FOR INJECTION if:

- you are allergic (hypersensitive) to sincalide or any or the other ingredients in SINCALIDE FOR INJECTION or component of the container.
- you must avoid meals that are high in fat, for example if you have: disorders of the
 pancreas, or gall bladder and its ducts; a gall bladder infection; gallbladder stones;
 appendicitis; organs with perforations (holes); infection or inflammation of the
 abdomen; ulcers, narrowing of the opening from the stomach to the small intestine,
 intestinal blockages or obstructions, any other blockages of the gastrointestinal tract;
 or severe abdominal pain.

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

- have ulcers of the gastrointestinal tract.
- have intestinal bleeding.
- have indigestion or reflux disease.
- will have any procedures where imaging of the gastrointestinal tract may be required since SINCALIDE FOR INJECTION can increase the movement of the dyes used in those procedures.
- have gall stones, particularly small gall stones which can become stuck in the bile ducts after you have been given SINCALIDE FOR INJECTION.
- are pregnant or planning to become pregnant. SINCALIDE FOR INJECTION may cause spontaneous abortion or premature labour if taken while pregnant.
- are breastfeeding or planning to breastfeed.

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

How to take SINCALIDE FOR INJECTION:

SINCALIDE FOR INJECTION will always be used in a hospital or clinic and will be given to you by a specially trained and qualified healthcare professional. They will tell you anything you need to know for its safe use.

Usual dose:

Your doctor will decide the dose that is best for you and for the type of procedure to be performed.

Overdose:

The symptoms of overdosage with SINCALIDE FOR INJECTION are likely to be mild and of short duration. Symptoms include abdominal discomfort, cramps, nausea, vomiting and diarrhea. Dizziness and flushing may also occur.

If you think you, or a person you are caring for, have received too much SINCALIDE FOR INJECTION, contact a healthcare professional, hospital emergency department, or regional poison control center immediately, even if there are no symptoms.

What are possible side effects from using SINCALIDE FOR INJECTION?

These are not all the possible side effects you may have when taking SINCALIDE FOR INJECTION. If you experience any side effects not listed here, tell your healthcare professional. Side effects may include:

- abdominal pain, cramps
- an urge to have a bowel movement
- bitter taste in the mouth
- headache
- flushing, sweating
- pain at the injection site
- shaking of the hands
- sneezing

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug
	Only if severe	In all cases	and get immediate medical help
Hypersensitivity (allergic reaction): fever, skin rash, hives, itching, swelling, shortness of breath, wheezing, nausea, vomiting, diarrhea, dizziness or fainting			✓

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/adverse-reaction-reporting.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 vials of SINCALIDE FOR INJECTION powder at room temperature (15° - 30°C). Keep out of reach and sight of children.

If you want more information about SINCALIDE FOR INJECTION:

- 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.avirpharma.com), or by calling 1-888-430-0436.

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