

BACK

several other CYP enzymes, including CYP1A2, CYP2B6 and CYP2C9. The active thiol metabolite binds rapidly and irreversibly to platelet receptors, thus inhibiting platelet aggregation for the remainder of the platelet's life span.

The active thiol metabolite is twice as high following a single 300 mg clopidogrel loading dose as its after four days of 75 mg maintenance dose. Cmax occurs approximately 30 to 60 minutes after dosing. In the 75 to 300 mg dose range, the pharmacokinetics of the active metabolite are linear. The active metabolite half-life is 8 to 12 hours and the terminal half-life of Cmax and AUC, respectively, are 21.6 and 27.4 hours.

Elimination

Following an oral dose of ¹⁴C-labeled clopidogrel in humans, approximately 50% of total radioactivity was excreted in urine and approximately 46% in feces over the 5 days post dosing. After a single 300 mg oral dose, approximately 70% of the radioactivity is excreted in urine over approximately 6 hours. The half-life of the active metabolite is about 30 minutes.

PRECLINICAL SAFETY DATA

In a non-rodent species, clopidogrel was administered to 75 mice and 104 weeks of age at doses that disasges up to 77 mg/kg per day, which afforded plasma exposures >25 times that in humans at the recommended daily dose of 75 mg.

Clopidogrel was not genotoxic in four *in vitro* tests (Ames test, Ames test with metabolic activation, sister chromatid exchange, Chinese hamster fibroblasts, and metaphase chromosome analysis of human lymphocytes) and in one *in vivo* test (micronucleus test) by oral route in mice.

Clopidogrel was found to have no effect on fertility of male and female rats treated prior to pairing and throughout gestation at oral doses up to 77 mg/kg per day (25 times the recommended human dose on an mg/m² basis).

PHARMACEUTICAL PARTICULARS

INCOMPATIBILITY

Not applicable.

SHELF LIFE

36 months

STORAGE CONDITION

Store at a temperature below 30°C. Protect from light & moisture

NATURE AND CONTENTS OF CONTAINER

10 tablets packed in Alu-Alu strip pack. 1 such strip is packed in a carton along with Package insert.

MANUFACTURING AUTHORISATION HOLDER AND MANUFACTURER

Manufacturing Authorization Holder	Manufacturer
Alanta Pharma Limited Alanta House, Charkop Kandivli (West) Mumbai - 400 067, India. Tel : +91-2431-664000 Fax : 022-4913 2070 Email : info@ajantapharma.com	Alanta Pharma Limited B-4-S-6, MIDC Industrial Area Palthan, Aurangabad, 431148 Dist: Aurangabad Maharashtra, India. Tel : +91-2431-664000 Fax : +91-2431-664100

Last Revision Date: Aug 18, 2023

INSTACLOP 75

Clopidogrel Tablets USP 75 mg Patient Information Leaflet

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet, you may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

What is this leaflet?

1. What Instaclop 75 is and what it is used for
2. What to do before you use Instaclop 75
3. How to use Instaclop 75
4. Possible side effects
5. How to store Instaclop 75
6. Contents of the pack and other information

1. **What Instaclop 75 is and what it is used for**
Instaclop 75 is a prescription medicine used to treat people who have any of the following:

- Heart attack
- Stroke

Instaclop 75 is used alone or with aspirin to lower your chance of having another serious problem with your heart or blood vessels such as heart attack, stroke, or blood clot that can lead to death.

Platelets are blood cells that help your blood clot normally. Instaclop 75 helps to keep platelets from sticking together and forming a clot that can block an artery.

It is not known if Instaclop 75 is safe and effective in children.

2. **What you need to know before you use Instaclop 75**
Instaclop 75 may not work as well in people who:

- Have certain genetic factors that affect how the body breaks down Instaclop 75.

Your doctor may do genetic tests to make sure Instaclop 75 is right for you.

- Take certain medicines, especially omeprazole (Prilosec) or esomeprazole (Nexium). Your doctor may change the medicine you take for stomach acid problems while you take Instaclop 75.

Instaclop 75 can cause serious and can sometimes lead to death.

Instaclop 75 is a blood thinner medicine that lowers the chance of blood clots forming. However, it may also cause you to bleed more easily.

- You may bruise and bleed more easily.
- You are more likely to have nose bleeds.
- It will take longer for any bleeding to stop.

Call your doctor right away if you have any of these signs or symptoms of bleeding:

- Unexpected bleeding or bleeding that lasts a long time
- Blood in your urine (pink, red or brown urine)
- Red or black stools (looks like tar)
- Bruises that happen without a known cause or get larger
- Cough up blood or blood clots
- Vomit blood or your vomit looks like coffee grounds

Do not stop taking Instaclop 75 without talking to the doctor who has prescribed it for you. Stopping suddenly may increase your chance of having a higher risk of having a heart attack or dying. If you must stop Instaclop 75 because of bleeding, your risk of a heart attack may be higher.

Do not take Instaclop 75 if you:

- Currently have a condition that causes bleeding, such as a stomach ulcer.
- Are allergic to clopidogrel or other ingredients in Instaclop 75.

Before you take Instaclop 75, tell your doctor if you:

- Have a history of bowel (gastrointestinal) or stomach ulcers.
- Have a history of bleeding problems.
- Plan to have surgery or a dental procedure.
- Are pregnant, or plan to become pregnant. It is not known if Instaclop 75 will harm your unborn baby.
- Are breastfeeding or plan to breastfeed. It is not known if Instaclop 75 passes into your breast milk. A decision should be made with your healthcare provider to avoid or discontinue breastfeeding when continuing Instaclop 75 is needed.

• Have had an allergy or reaction to any medicine used to treat your disease.

• Have had stomach and/or chest pain that gets up being reaction including skin reactions while taking Instaclop 75. These are not all the possible side effects of Instaclop 75. For more information, ask your doctor or pharmacist. Call your doctor for medical advice about side effects.

3. **How to take Instaclop 75**
Take Instaclop 75 exactly as your doctor tells you. Do not change your dose or stop taking Instaclop 75 without talking to your doctor. Taking Instaclop 75 may increase your risk of heart attack or stroke.

• If you miss a dose, take Instaclop 75 as soon as you remember. If it is almost time for your next dose, skip the missed dose. Take Instaclop 75 as your regular doses. Do not take extra doses of Instaclop 75 to make up for missed doses.

• If you take too much Instaclop 75, call your doctor or go to the nearest emergency room right away.

• Talk with your doctor about stopping your Instaclop 75 before you have surgery. Your doctor may tell you to stop taking Instaclop 75 before you have surgery if you have surgery to avoid excessive bleeding during surgery.

4. **Possible side effects**
Instaclop 75 can cause serious side effects including bleeding. Some of the possible side effects of Instaclop 75 include:

- **Thrombocytopenic Purpura (TTP).** TTP can happen with Instaclop 75, sometimes after a short time (less than 2 weeks). TTP is a blood clotting problem where blood clots form in blood vessels, and can lead to kidney failure, stroke, and even cause death. Get medical help right away because it may cause death. Get medical help right away if you have any of these symptoms and they cannot be explained by another medical condition:
- Purplish spots (called purpura) on the skin or in the mouth (mucous membranes) due to bleeding under the skin
- Yellowing of the whites of your eyes or yellow (jaundice)
- Very dark urine
- Your skin feels very pale
- Fever
- Fast heart rate or feeling short of breath
- Headache
- Speech changes

• Confusion

- Coma
- Stroke
- Seizure
- Low amount of urine, or urine that is pink or has blood in it
- Stomach area (abdominal) pain
- Nausea, vomiting, or diarrhea
- Vision changes
- Persistent low blood sugar symptoms
- Tiredness or weakness
- Allergic reaction that bothers you, or that does not go away. Tell your doctor if you develop an allergic reaction including skin reactions while taking Instaclop 75. These are not all the possible side effects of Instaclop 75. For more information, ask your doctor or pharmacist. Call your doctor for medical advice about side effects.

5. **How to store Instaclop 75**
Keep this medicine out of the sight and reach of children. Store at a temperature below 30°C. Protect from light & moisture. Do not use this medicine after the expiry date which is stated on the carton and blister after EXP. The expiry date refers to the last day of that month.

6. **Contents of the pack and other information**
Each Instaclop 75 strip contains 10 tablets.
Each film coated tablet contains: Clopidogrel Bisulfate USP equivalent to Clopidogrel 75 mg

List of Excipients:
Polyethylene Glycol 6000, Isopropyl Alcohol, Microcrystalline Cellulose (LH-51), Mennion (Prestitol 200SD), Aerosol R372, Croscarmellose Sodium, Magnesium Stearate, Wincostat, WP-1214, Methylene chloride and Purified Water.

What Instaclop 75 looks like and contents of the pack
10 tablets packed in Alu-Alu strip pack. 1 such strip is packed in a carton along with Package insert.

7. **Manufacturer**
Alanta Pharma Limited
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For any information about this medicinal product, please contact Manufacturing/Authorization Holder.

DATE OF PUBLICATION OR REVISION
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INSTACLOP 75
(Clopidogrel Tablets USP 75 mg)

Patient Information Leaflet

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- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

What is in this leaflet?

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2. What you need to know before you use Instaclop 75
3. How to use Instaclop 75
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6. Contents of the pack and other information

1. What Instaclop 75 is and what it is used for

Instaclop 75 is a prescription medicine used to treat people who have any of the following:

- Chest pain due to heart problems
- Poor circulation in their legs (peripheral arterial disease)
- A heart attack
- A stroke

Instaclop 75 is used alone or with aspirin to lower your chance of having another serious problem with your heart or blood vessels such as heart attack, stroke, or blood clot that can lead to death.

Platelets are blood cells that help your blood clot normally. Instaclop 75 helps to prevent platelets from sticking together and forming a clot that can block an artery.

It is not known if Instaclop 75 is safe and effective in children.

2. What you need to know before you use Instaclop 75

Instaclop 75 may not work as well in people who:

- have certain genetic factors that affect how the body breaks down Instaclop 75.

Your doctor may do genetic tests to make sure Instaclop 75 is right for you.

- take certain medicines, especially omeprazole (Prilosec) or esomeprazole (Nexium). Your doctor may change the medicine you take for stomach acid problems while you take Instaclop 75.

Instaclop 75 can cause bleeding which can be serious and can sometimes lead to death. Instaclop 75 is a blood thinner medicine that lowers the chance of blood clots forming in your body. While you take Instaclop 75:

- You may bruise and bleed more easily
- You are more likely to have nose bleeds
- It will take longer for any bleeding to stop

Call your doctor right away if you have any of these signs or symptoms of bleeding:

- Unexpected bleeding or bleeding that lasts a long time
- Blood in your urine (pink, red or brown urine)
- Red or black stools (looks like tar)
- Bruises that happen without a known cause or get larger
- Cough up blood or blood clots
- Vomit blood or your vomit looks like coffee grounds

Do not stop taking Instaclop 75 without talking to the doctor who prescribes it for you. People who stop taking Instaclop 75 too soon have a higher risk of having a heart attack or dying. If you must stop Instaclop 75 because of bleeding, your risk of a heart attack may be higher.

Do not take Instaclop 75 if you:

- Currently have a condition that causes bleeding, such as a stomach ulcer
- Are allergic to clopidogrel or other ingredients in instaclop 75.

Before you take Instaclop 75, tell your doctor if you:

- Have a history of bowel (gastrointestinal) or stomach ulcers.
- Have a history of bleeding problems.
- Plan to have surgery or a dental procedure.
- Are pregnant or plan to become pregnant. It is not known if instaclop 75 will harm your unborn baby.
- Are breastfeeding or plan to breastfeed. It is not known if instaclop 75 passes into your breast milk. A decision should be made with your healthcare provider to avoid or discontinue breastfeeding when continuing instaclop 75 is needed.
- Have had an allergy or reaction to any medicine used to treat your disease.

Tell all of your doctors and your dentist that you are taking Instaclop 75. They should talk to the doctor who prescribed Instaclop 75 for you before you have any surgery or invasive procedure.

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

Instaclop 75 may affect the way other medicines work, and other medicines may affect how Instaclop 75 works.

Instaclop 75 may increase blood levels of other medicines such as repaglinide

Taking Instaclop 75 with certain other medicines may increase your risk of bleeding.

Especially tell your doctor if you take:

- Aspirin, especially if you have had a stroke. Always talk to your doctor about whether you should take aspirin along with instaclop 75 to treat your condition.
- Nonsteroidal anti-inflammatory drugs (NSAIDs). Ask your doctor or pharmacist for a list of NSAID medicines if you are not sure.
- Warfarin (Coumadin, Jantoven).
- Selective serotonin reuptake inhibitors (SSRIS) and serotonin norepinephrine reuptake inhibitors (SNRIS). Ask your doctor or pharmacist for a list of SSRI or SNRI medicines if you are not sure.
- Rifampin (used to treat severe infections)
- Other antiplatelet agents

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

3. How to use Instaclop 75

- Take Instaclop 75 exactly as your doctor tells you.
- Do not change your dose or stop taking Instaclop 75 without talking to your doctor first, stopping Instaclop 75 may increase your risk of heart attack or stroke.
- Take Instaclop 75 with aspirin as instructed by your doctor.
- If you miss a dose, take Instaclop 75 as soon as you remember. If it is almost time for your next dose, skip the missed dose. Take the next dose at your regular time. Do not take 2 doses of Instaclop 75 at the same time unless your doctor tells you to.
- If you take too much Instaclop 75, call your doctor or go to the nearest emergency room right away.
- Talk with your doctor about stopping your Instaclop 75 before you have surgery. Your doctor may tell you to stop taking Instaclop 75 at least 5 days before you have surgery to avoid excessive bleeding during surgery.

4. Possible side effects

Instaclop 75 can cause serious side effects including:

A blood clotting problem called Thrombotic Thrombocytopenic Purpura (TTP). TTP can happen with Instaclop 75, sometimes after a short time (less than 2 weeks). TTP is a blood clotting problem where blood clots form in blood vessels; and can happen anywhere in the body. TTP needs to be treated in a hospital right away because it may cause death. Get medical help right away if you have any of these symptoms and they cannot be explained by another medical condition:

- Purplish spots (called purpura) on the skin or in the mouth (mucous membranes) due to bleeding under the skin
- Your skin or the whites of your eyes are yellow (jaundice)
- You feel tired or weak
- Your skin looks very pale
- Fever
- Fast heart rate or feeling short of breath
- Headache
- Speech changes

- Confusion
- Coma
- Stroke
- Seizure
- Low amount of urine, or urine that is pink or has blood in it
- Stomach area (abdominal) pain
- Nausea, vomiting, or diarrhea
- Vision changes
- Persistent low blood sugar symptoms

Tell your doctor if you have any side effect that bothers you or that does not go away. Tell your doctor if you develop an allergic reaction including skin reactions while taking Instaclop 75.

These are not all the possible side effects of Instaclop 75. For more information, ask your doctor or pharmacist. Call your doctor for medical advice about side effects.

5. How to store Instaclop 75

Keep this medicine out of the sight and reach of children.

Store at a temperature below 30°C. Protect from light & moisture.

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6. Contents of the pack and other information

What Instaclop 75 contains:

Each film coated Tablet contains:
 Clopidogrel Bisulfate USP
 equivalent to Clopidogrel.....75 mg

List of Excipients:

Polyethylene Glycol 6000, Isopropyl Alcohol, Microcrystalline Cellulose (Avicel PH 112), Low Substituted Hydroxypropyl Cellulose (LH-31), Mannitol (Pearlitol 200SD), Aerosil R972 Pharma, Sodium Stearyl Fumarate, Wincoat WT-1274, Methylene chloride and Purified Water.

What Instaclop 75 looks like and contents of the pack

10 tablets packed in Alu-Alu strip pack, 1 such strip is packed in a carton along with Package insert.

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Ajanta Pharma Limited Ajanta House, Charkop Kandivli (West) Mumbai - 400 067, India. Tel : 022-6913 2111/2112 Fax : 022-6913 2070 Email : info@ajantapharma.com	Ajanta Pharma Limited B-4-5-6, MIDC Industrial Area Paithan, Aurangabad, 431 148 Maharashtra, India Tel : +91-2431-664000 Fax : +91-2431-664100

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