

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PATIENT MEDICATION INFORMATION

Pr **ACETAMINOPHEN INJECTION**
Acetaminophen injection
10 mg/mL

Read this carefully before you start taking **ACETAMINOPHEN 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 **ACETAMINOPHEN INJECTION**.

Serious Warnings and Precautions

Liver Injury

- This product contains acetaminophen
- Acetaminophen can be found in
 - oral solutions / drops
 - syrups
 - pills
 - capsules
 - suppositories
 - intravenous solutions, etc.
- Taking more than the maximum daily dose can lead to serious liver problems.
- Based on your body weight, your doctor will tell you how much acetaminophen to take in a day.
- Read the labels on all products you take to see if they contain acetaminophen
 - Use the labels to calculate how much acetaminophen you have had in a day
 - Keep track of how much acetaminophen is in each dose and how much you have taken in 24 hours

What is **ACETAMINOPHEN INJECTION** used for?

It relieves pain and fever.

- **Adults and Children (2 years of age and older)**
 - The short-term relief of mild to moderate pain. Acetaminophen Injection will be used when your healthcare professional feels it is necessary to give by injection into a vein.
 - the relief of moderate to severe pain when used with narcotic pain relievers
 - the treatment of fever
- **Children less than 2 years of age**

- ACETAMINOPHEN INJECTION is not recommended for children less than 2 years old.

How does ACETAMINOPHEN INJECTION work?

ACETAMINOPHEN INJECTION is believed to work by blocking chemical messengers in the brain that cause pain and fever.

What are the ingredients in ACETAMINOPHEN INJECTION?

Medicinal ingredient: Acetaminophen, also known as APAP or paracetamol.

Non-medicinal ingredients: Mannitol, povidone K12, sodium dihydrogen phosphate dihydrate, sodium hydroxide and water

ACETAMINOPHEN INJECTION comes in the following dosage forms:

Solution for intravenous infusion 10 mg / mL

Do not use ACETAMINOPHEN INJECTION if you:

- are allergic to acetaminophen or any other ingredient in this product
- suffer from severe liver problems or severe active liver disease

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

- have taken other medications containing acetaminophen in the past 24 hours
- suffer from active liver disease or have liver problems
- suffer from severe kidney problems
- suffer from alcoholism
- suffer from malnutrition
- are allergic to acetaminophen or to any of the other ingredients of ACETAMINOPHEN INJECTION.
- have recently lost blood
- think you are dehydrated
- are taking warfarin (a blood thinner)
- are pregnant or breast-feeding

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

You should be careful when taking the following drugs with ACETAMINOPHEN INJECTION:

- alcohol
- probenecid
- barbiturates
- zidovudine
- carbamazepine
- isoniazid
- diflunisal
- imatinib
- sorafenib
- busulfan
- Long term use of oral acetaminophen at a maximum dose per day may cause an increased risk of the side effects of warfarin (e.g., bleeding)

How to take ACETAMINOPHEN INJECTION:

You will be given ACETAMINOPHEN INJECTION as an injection into your vein by a healthcare professional. Over the counter products containing acetaminophen should not be taken when you are given ACETAMINOPHEN INJECTION. Your healthcare professional will determine the best dose for you based on your weight.

Usual dose:

- Adults and adolescents weighing 50 kg and over: 1000 mg every 6 hours.
- Adults and adolescents weighing under 50 kg: 15 mg/kg every 6 hours.
- Children between 2 to 12 years of age: 15 mg/kg every 6 hours.

Maximum daily dose:

- Adults and adolescents weighing 50 kg and over: 4000 mg in 24 hours
- Adults and adolescents weighing under 50 kg: 75 mg/kg in 24 hours (up to 3750mg)
- Children between 2 to 12 years of age: 75 mg/kg in 24 hours

ACETAMINOPHEN INJECTION is not recommended for children less than 2 years of age.

Overdose:

If you think you have been given too much **ACETAMINOPHEN INJECTION**, contact your healthcare professional, hospital emergency department or regional poison control centre immediately, even if there are no symptoms. Quick medical attention is critical even if you do not notice any signs or symptoms.

If you have an overdose while receiving ACETAMINOPHEN INJECTION, you may experience the following:

- nausea
- vomiting
- sweating
- general feeling of discomfort

If these happen, seek medical help immediately.

Overdose of ACETAMINOPHEN INJECTION can cause:

- liver damage
- kidney damage
- low blood sugar
- low platelet count

What are possible side effects from using ACETAMINOPHEN INJECTION?

These are not all the possible side effects you may feel when you are given ACETAMINOPHEN INJECTION. If you experience any side effects not listed here, contact your healthcare professional.

Like all medicines, ACETAMINOPHEN INJECTION may cause side effects, but not everybody gets them.

Side effects in adults include:

- Nausea
- Vomiting
- Headache
- Difficulty sleeping

Side effects in children include:

- Nausea
- Vomiting
- Constipation
- Itchy skin
- Agitation
- Lung collapse

It is important to tell your health professional if you have any medical conditions.

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
RARE			
Following overdose, nausea,		✓	

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
vomiting, sweating, and general discomfort may be experienced			
Anaphylactic shock (immediate violent allergic reaction)			✓
Hypotension (low blood pressure)		✓	
Neutropenia (depletion of a type of white blood cells)		✓	
Urticaria (a kind of skin rash also called hives)	✓		
Angioedema (swelling of a tissue such as the lips, eyes, joints)		✓	
Respiratory distress		✓	
Thrombocytopenia (depletion of platelets in blood)		✓	
VERY RARE			
Serious Skin Reactions (Stevens-Johnson Syndrome, Toxic Epidermal Necrolysis, Acute Generalized Exanthematous Pustulosis): any combination of itchy skin rash, redness, blistering and peeling of the skin and/or of the lips, eyes, mouth, nasal passages or genitals, accompanied by fever, chills, headache, cough, body aches or joint pain, yellowing of the skin or eyes, dark urine			✓
Liver Injury (yellowing of the skin or eyes, dark urine, abdominal pain, nausea, vomiting, loss of appetite)		✓	
UNKNOWN FREQUENCY			
Allergic reaction (symptoms like swelling of the face, lip or throat, rash, itchiness, hives, difficulty breathing or wheezing)			✓

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to 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:

ACETAMINOPHEN INJECTION will be stored by healthcare professionals. It will be stored in the original container including metalized overpack at room temperature (15 to 30°C). Do not refrigerate or freeze. Protect from light. The healthcare professional will give it to you immediately after opening.

ACETAMINOPHEN INJECTION is for single use only: discard unused portion.

Keep out of reach and sight of children.

If you want more information about ACETAMINOPHEN 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://health-products.canada.ca/dpd-bdpp/index-eng.jsp>); the manufacturer's website www.avirpharma.com, or by calling 1-800-363-7988.

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