

CONSUMER INFORMATION

ANACIN[®]

325 mg of Acetylsalicylic acid (ASA)
and 32 mg of Caffeine Tablets

This leaflet is a summary and will not tell you everything about **ANACIN[®]**. Contact your physician or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:

ANACIN[®] is for the fast relief of headaches, fever, mild to moderate aches, arthritic and rheumatic pain, toothaches and menstrual pain.

What it does:

ANACIN[®] is for a fast and effective relief of pain.

What the medicinal ingredients are:

Acetylsalicylic acid (ASA) and caffeine

What the important non-medicinal ingredients are:

Cellulose, corn starch, polyethylene glycol, sodium lauryl sulphate, hypolose, hypromellose, methylcellulose.

What dosage forms it comes in:

ANACIN[®] comes in tablets.

WARNINGS AND PRECAUTIONS

Do not take ANACIN[®] if you:

- are allergic to salicylates or any of the non-medicinal ingredients in the formulation;
- are allergic to any other non-steroidal anti-inflammatory drugs (NSAIDs) or other pain relievers/fever reducers;
- have an ulcer or a history of ulcers;
- are prone to bleeding;
- have active or severe liver or kidney disease;
- have a history of asthma induced by salicylates or other NSAIDs;
- are using methotrexate at doses of 15 mg/week or more;
- are in your last trimester of pregnancy.

Do not use with other drugs containing acetylsalicylic acid or other salicylates, or other NSAIDs (e.g. ibuprofen, naproxen).

Stomach bleeding warning: This product contains a nonsteroidal anti-inflammatory drug (NSAID) which **may cause severe stomach bleeding.**

Keep out of the reach of children. This package contains sufficient medication to seriously harm a child. **Do not give** to children and teenagers less than 18 years of age who have chicken pox, cold or flu symptoms before a physician or a pharmacist is consulted about Reye's syndrome, a rare but serious illness reported to be associated with ASA.

Consult a physician or pharmacist before use if you:

- have a history of stomach problems such as heartburn;
- have asthma, high blood pressure, heart disease, liver or kidney disease, gout, severe anemia or any other serious conditions;
- have glaucoma;
- have overactive bladder syndrome;
- are taking acetaminophen, anticonvulsants, blood thinners (anticoagulants), diuretics, medication for arthritis, diabetes or gout, methotrexate, steroids, or any other medication;
- have 3 or more alcoholic drinks per day;
- are trying to conceive, are pregnant or nursing;
- are having surgery in 5 to 7 days;
- are 60 years or older.

Consult a physician or pharmacist if:

- your pain lasts more than 5 days, or fever lasts more than 3 days;
- new symptoms occur or if redness or swelling is present.

PROPER USE OF THIS MEDICATION

How to Take ANACIN[®]

Adult dose: Take 1 or 2 tablets with a glass (250 ml) of water every 4 to 6 hours. Do not exceed 12 tablets in 24 hours.

Do not take more than the recommended dose unless advised by your physician. Use the smallest effective dose.

Avoid other caffeine-containing products. Too much caffeine may cause rapid heart rate, nervousness or sleeplessness.

In case of overdose: call a poison control centre or physician immediately, even if you do not notice any signs or symptoms.

SERIOUS SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Stop use and consult a physician if any of the following occur:

- an allergic reaction which may include: itching, skin rashes or hives, wheezing or trouble breathing, swelling in the face;
- you experience any of the following signs of stomach bleeding:
 - feel faint, vomit blood, have bloody or black stools;
 - have stomach pain that does not get better;
- any loss of hearing or ringing or buzzing in the ears.

HOW TO STORE IT

Keep out of the reach of children.

Store at room temperature (15°C to 30°C).

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- Report online at www.healthcanada.gc.ca/medeffect
- Call toll-free at 1-866-234-2345
- Complete a Canada Vigilance Reporting Form and:
 - Fax toll-free to 1-866-678-6789, or
 - Mail to: Canada Vigilance Program
Health Canada
Postal Locator 0701D
Ottawa, Ontario
K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at www.healthcanada.gc.ca/medeffect.

NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

For more information, contact the sponsor, Paladin Labs Inc., at 1-888-867-7426.

This leaflet was prepared by Paladin Labs Inc.



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Last revised: August 2017

301613-01

