

APFEN PLUS
200mg/12.8mg Film Coated Tablets
Ibuprofen/CodeinePhosphate Hemihydrate

PATIENT INFORMATION LEAFLET.

WHAT YOU SHOULD KNOW ABOUT THIS MEDICINE.

Read all of this leaflet carefully because it contains important information for you.

This medicine is available without a prescription. However, you still need to use Apfen Plus Tablets carefully to get the best results from them.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must contact your doctor if your symptoms do not improve after three days.
- If any of the side effects get serious or if you notice any side effect not listed in this leaflet, please tell your doctor or pharmacist.

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1. What are Apfen Plus Tablets and what are they for

Apfen Plus Tablets contain **ibuprofen** and **codeine**, which are both pain killing drugs. By working on your body in different ways ibuprofen and codeine combine to relieve pain. **Ibuprofen** also helps to reduce swelling and inflammation in sore muscles etc.

Apfen Plus Tablets provides effective relief from moderate pain, such as joint, muscle and back pain, arthritis, rheumatism, headaches (including migraine), toothache and severe period pains.

Codeine can be used in children over 12 years of age for the short-term relief of moderate pain that is not relieved by other painkillers such as paracetamol or ibuprofen alone.

This product contains codeine. Codeine belongs to a group of medicines called opioid analgesics which act to relieve pain. It can be used on its own or in combination with other pain killers such as paracetamol.

2. Check before you take Apfen Plus Tablets

Anti-inflammatory/pain-killer medicines like ibuprofen may be associated with a small increased risk of heart attack

‘myocardial infarction’ or stroke, particularly when used at high doses.

. Do not exceed the recommended dose or duration of treatment.

You should discuss your treatment with your doctor or pharmacist before taking Apfen plus if you:

- have heart problems including heart failure, angina (chest pain), or if you have had a heart attack, bypass surgery, peripheral artery disease (poor circulation in the legs or feet due to narrow or blocked arteries), or any kind of stroke (including ‘mini-stroke’ or transient ischaemic attack “TIA”).

- have high blood pressure, diabetes, high cholesterol, have a family history of heart disease or stroke, or if you are a smoker..

During chicken pox (varicella) it is advisable to avoid the use of ibuprofen.

The product belongs to a group of medicines (NSAIDs) which may impair the fertility in women.

This effect is reversible on stopping the medicine.

There is a risk of renal impairment in dehydrated adolescents.

Do NOT take Apfen Plus Tablets if you:

- are allergic to ibuprofen, codeine or any of the other ingredients listed in Section 6.
- are under 12 years old, due to the risk of severe breathing problems.
- are allergic to aspirin or other anti-inflammatory drugs.
- have or have ever had a stomach ulcer, perforation or bleeding.
- suffer from severe liver or kidney problems.
- suffer from heart failure.
- suffer from severe asthmatic attacks or severe breathing problems.
- suffer from hypertension, heart failure or lung disease.
- suffer from a disease known as systemic lupus erythematosus.
- suffer from Crohn's disease.
- have recently had a head injury.
- have recently had gall bladder surgery or a similar operation.
- have raised pressure in the brain.
- are taking monoamine oxidase inhibitors (drugs used to treat depression) or you have taken monoamine oxidase inhibitors within the last 14 days.
- are taking medicines to thin your blood, such as warfarin.
- are taking other anti-inflammatory medicines, such as corticosteroids.
- are an alcoholic.
- are in the last 3 months of pregnancy..
- are breastfeeding. The use of codeine containing products while breastfeeding may harm your baby.
- have or have ever had a stomach ulcer, perforation or bleeding.
- Codeine is transformed to morphine in the liver by an enzyme. Morphine is the substance that produces pain relief. Some people have a variation of this enzyme and this can affect people in different ways. In some people, morphine is not produced or produced in very small quantities, and it will not provide enough pain relief. Other people are more likely to get serious side effects because a very high amount of morphine is produced. If you notice any of the following side effects, you must stop taking this medicine and seek immediate medical advice: slow or shallow breathing, confusion, sleepiness, small pupils, feeling or being sick, constipation, lack of appetite
- Codeine should not be used for pain relief in children and adolescents after removal of their tonsils or adenoids due to Obstructive Sleep Apnoea Syndrome
- Codeine is not recommended in children with breathing problems, since the symptoms of morphine toxicity may be worse in these children

[!]Take special care with Apfen Plus Tablets:****

If your symptoms continue you should consult your doctor.

You should not use this medicine for more than 3 days except on the advice of your doctor or pharmacist.

- if you are elderly and/or are in poor health.
- if you suffer from an enlarged prostate (difficulty passing water).
- if you suffer from any bowel problems.
- if you suffer from Addison's disease (a rare hormonal disease).
- if you suffer from any liver or kidney problems.
- if you are allergic to aspirin or to any other non-steroidal anti-inflammatory drugs.
- If you have low blood pressure or an underactive thyroid gland.

Only use this medicine if you are suffering from moderate pain. Taking a pain reliever for too often or too long can make it worse.

If you have been told by your doctor that you have intolerance to some sugars contact your doctor before taking this medicinal product.

Speak with your doctor if you suspect or know that you are pregnant before taking this medicine.

[!]Taking other medicines with Apfen Plus Tablets:****

If you are taking, or have recently taken any other medicines, including other medicines obtained without a prescription tell your pharmacist or doctor before taking Apfen Plus Tablets. Apfen Plus Tablets may affect or be affected by some other medicines. For example:

- medicines that you have bought yourself such as other painkillers. Many of these will contain ibuprofen and/or **codeine** and must not be taken while you are taking Apfen Plus Tablets.
- Medicines that contain **aspirin**, unless your doctor has advised you to take low-dose aspirin (75mg daily).
- any other medicines that might affect your liver. Always check the leaflet that comes with your other medicine.
- medicines for the treatment of depression or anxiety, or medicines known as tranquilisers or lithium.
- medicines to help you sleep.
- medicine for high cholesterol levels or for the treatment of diarrhoea (cholestyramine).
- medicines to stop you feeling sick or vomiting (domperidone or metoclopramide).
- medicines that are anti-coagulants (i.e. thin blood/prevent clotting e.g. aspirin/acetylsalicylic acid, warfarin, ticlopidine).
- medicines to reduce high blood pressure (ACE-inhibitors such as captopril, beta-blockers such as atenolol medicines, angiotensin-II receptor antagonists such as losartan • medicines to reduce fluid retention (diuretics).
- medicines to treat HIV/AIDS (such as zidovudine).

Some other medicines may also affect or be affected by the treatment of Apfen Plus. You should therefore always seek the advice of your doctor or pharmacist before you use Apfen Plus with other medicines.

[!]Taking Apfen Plus Tablets with food and drink:****

- You should avoid alcohol when taking Apfen Plus Tablets.

[!]Pregnancy and breastfeeding****

Do not take Apfen Plus Tablets if you are breastfeeding. Codeine and morphine passes into breast milk.

Do not take Apfen Plus tablets in the last 3 months of pregnancy. Speak to your doctor if you are in the first 6 months of pregnancy before taking this medicine.

[!]Driving and using machines:****

Apfen Plus Tablets may make you feel drowsy. You should not drive or operate machinery until you know how they affect you.

3. How to take Apfen Plus Tablets

How many tablets should I take and how often?

Swallow Apfen Plus Tablets with water.

Adults, including elderly people and children aged 12 years and over:

- Take one to two tablets three times a day.
- Do not take them more often than every 6 hours.
- **Do not take more than 6 tablets in 24 hours.**

If you are elderly your doctor may recommend a lower dose.

NOT SUITABLE FOR CHILDREN UNDER 12 YEARS OF AGE.

Do not exceed the stated dose.

Do not take for more than 3 days. If pain does not improve after 3 days, talk to your doctor for advice.

What should I do if I forget to take a dose?

Do **NOT** take a double dose to make up for a dose you have forgotten.

You must allow at least 6 hours between doses.

If you have taken more than the recommended dose you must contact your doctor or

At high doses this medicine can cause serious side-effects.

pharmacist immediately and say exactly how much you have taken. Your doctor or pharmacist will advise you what to do.

4. Possible side-effects

Like all medicines, Apfen Plus Tablets can have side effects, although not everybody gets them.

The medicine may make you feel dizzy or drowsy. These effects may be relieved by lying down.

The medicine may also give you headaches and ringing in your ears (tinnitus).

You may also have stomach pains and feel sick or vomit, or have diarrhoea. You may also become constipated. You may experience problems with your blood which mean that you may bleed or bruise easily (known as thrombocytopenia) or which make it more likely that you may get an infection (known as agranulocytosis), or worsening of colitis or Crohn's disease.

Medicines such as Apfen Plus may be associated with a small increased risk of heart attack 'myocardial infarction' or stroke. Blood disorders, swelling, high blood pressure, heart failure and blurred vision have also been reported.

Some patients with existing auto-immune disorders may experience a severe headache, stiff neck, nausea, vomiting, fever or confusion.

Occasionally this medicine may cause an allergic reaction – such as a skin rash, itching, swelling or shortness of breath. These effects go away once you stop taking the medicine.

If any of these effects occur, stop taking the medicine, and tell your doctor or pharmacist immediately.

This product contains **codeine**. This medicine should only be taken when necessary. Do not take more than the stated dose and do not take every day for more than 3 days unless told to do so by your doctor. Prolonged regular use can lead to addiction and result in withdrawal symptoms, such as restlessness and irritability once the drug is stopped. If you find you need to use this product all the time, you must see your doctor.

Reporting side effects

If you get any side effects, tell your doctor, pharmacist or nurse. This includes any side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E- mail: medsafety@hpra.ie.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store this medicine

- No special storage precautions are required.
- Keep out of the sight and reach of children.
- Do not use this medicine after the expiry date (EXP) which is stated on the blister and carton. The expiry date refers to the last day of that month.
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help protect the environment.

Remember:

As with all medicines, **do NOT share** your medicine with anyone else.

6. Further information

What Apfen Plus Tablets contain:

Apfen Plus Tablets contain 200mg of ibuprofen and 12.8mg of codeine phosphate hemihydrate. The tablet cores also contain microcrystalline cellulose, hydrogenated vegetable oil, sodium starch glycolate, colloidal silica, lactose, cellulose. The tablet coating contains hypromellose and macrogol 400.

What Apfen Plus looks like and contents of the pack:

Apfen Plus Tablets are white, film-coated, capsule-shaped tablets, which are embossed on one side with '+'. They are available in packs of 4, 6, 10, 12, 16, 20, 24, 30, 32, 48, 60, 96, 100 and 108 tablets.

Not all pack sizes may be marketed.

Product authorisation holder and manufacturer:

The Product authorisation holder is:

GlaxoSmithKline Consumer Healthcare (Ireland) Limited,
12 Riverwalk, CityWest Business Campus, Dublin 24.

The manufacturer is:

GlaxoSmithKline Dungarvan Limited, Knockbrack, Dungarvan, Co. Waterford.

This leaflet was last revised in August 2017.

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