PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S2

ADCO FLUPAIN, Syrup

Triprolidine HCl 0,625 mg; Pseudoephedrine HCl 15 mg and Paracetamol 125 mg

Preservatives: Methylparaben 0,12 % *m/v* and Propylparaben 0,02 % *m/v*

Contains alcohol: 0,5 % *v/v*

Contains sweetener: Saccharin Sodium 0,01 g

Contains sorbitol 70 % solution 1,5 g

Sugar free

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

ADCO FLUPAIN is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to take ADCO FLUPAIN carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share ADCO FLUPAIN with any other person.
- Ask your pharmacist if you need more information or advice.
- You must see a doctor if your child's symptoms worsen or do not improve after 10 days.

What is in this leaflet

1. What ADCO FLUPAIN is and what it is used for

2. What you need to know before you take ADCO FLUPAIN

3. How to take ADCO FLUPAIN

4. Possible side effects

5. How to store ADCO FLUPAIN

6. Contents of the pack and other information.

1. What ADCO FLUPAIN is and what it is used for

ADCO FLUPAIN provides symptomatic relief of colds and flu associated with cough in children 2 years and older.

Paracetamol is used to relieve pain and reduce fever associated with colds and flu.

Pseudoephedrine hydrochloride works by narrowing the blood vessels, leading to clearing of nasal congestion.

Triprolidine is an antihistamine, which works by preventing the effects of a substance produced by the body called histamine.

2. What you need to know before you give ADCO FLUPAIN

Do not give ADCO FLUPAIN:

- If your child has a hypersensitivity (allergic) to paracetamol, pseudoephedrine hydrochloride, triprolidine or any of the other ingredients of ADCO FLUPAIN (listed in section 6).
- If your child has a heart disease.
- If your child has thyrotoxicosis (a condition that happens when you have too much thyroid hormone in your body showing signs of unexplained weight loss, a rapid heart rate and shakiness).
- If your child has disease of the prostate gland or bladder dysfunction.
- If your child has damage to the nerve in the eye caused by pressure inside the eye rising rapidly because fluid cannot drain out.
- If your child has pheochromocytoma (tumor of special glands most often found in the adrenal glands).
- If your child is taking monoamine oxidase inhibitor treatment (certain medicines used for depression), or within 14 days of such treatment.
- If your child is under 2 years of age.
- During an asthma attack.
- If your child is inhaling anaesthetic during surgery.
- If your child has very high blood pressure (severe hypertension) or hypertension not controlled by your medication.
- If your child has severe acute (sudden) or chronic (long-term) kidney disease or kidney failure.

Warnings and precautions

Take special care with ADCO FLUPAIN

- ADCO FLUPAIN contains paracetamol. Do not give your child more than the recommended dosage, this may cause severe damage to the liver. Consult your doctor if no relief is obtained with the recommended dosage.
- If your child suffers from liver disease, do not give paracetamol-containing preparations without consulting a doctor.
- Do not use continuously for longer than 10 days without consulting your doctor.
- If you have child has an overactive thyroid.
- If your child has high blood sugar.
- If your child has serious kidney or liver impairment.
- Serious skin reactions such as toxic epidermal necrolysis (TEN), Stevens-Johnson syndrome (SJS), acute generalized exanthematous pustulosis (AGEP), drug reaction with eosinophilia and systemic symptoms (DRESS)/Drug-induced hypersensitivity syndrome (DIHS) and fixed drug eruptions (FDE) acute generalized exanthematous pustulosis (AGEP), Stevens-Johnson syndrome (SJS), and toxic epidermal necrolysis (TEN), have been reported in patients receiving paracetamol. If your child experiences any signs of serious skin reactions such as swelling, itching, red severe rash, stop using ADCO FLUPAIN immediately and contact your doctor (see Section 4).
- Cases of posterior reversible encephalopathy syndrome (PRES) and reversible cerebral vasoconstriction syndrome (RCVS) have been reported following use of medicines containing pseudoephedrine. PRES and RCVS are rare conditions that can involve reduced blood supply to the brain. Stop using ADCO FLUPAIN immediately and seek immediate medical assistance if you develop symptoms that may be signs of PRES or RCVS (see section 4 "Possible side effects" for symptoms).

ADCO FLUPAIN contains glycerol

May cause headache, stomach upset and diarrhoea.

ADCO FLUPAIN contains sorbitol

If you have been told that you have an intolerance to some sugars, you should not take ADCO FLUPAIN.

This medicine contains 990 mg sorbitol in each 5 ml dosage unit, which is equivalent to 200 mg/ml. Sorbitol

is a source of fructose. If your doctor has told you that your child has an intolerance to some sugars or if you have been diagnosed with hereditary fructose intolerance (HFI), a rare genetic disorder in which a person cannot breakdown fructose, talk to your doctor before your child takes or receives this medicine.

ADCO FLUPAIN contains propylene glycol

This medicine contains 25 mg propylene glycol in each 5 ml dosage unit, which is equivalent to 5 mg/ml. If your child is less than 5 years old, talk to your doctor or pharmacist before giving them this medicine, in particular if they use other medicines that contain propylene glycol or alcohol.

ADCO FLUPAIN contains ethanol

This medicine contains 19.7 mg alcohol (ethanol) in each 5 ml dose, which is equivalent to 3.9 mg/ml (0.39 % *w/v).* The amount in a 5 ml dose of this medicine is equivalent to less than 0.5 ml beer or 0.2 ml wine. The small amount of alcohol in this medicine will not have any noticeable effects.

Other medicines and ADCO FLUPAIN

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

- ADCO FLUPAIN should be used with caution in patients taking other *sympathomimetic agents*, such as *decongestants*, *appetite suppressants* and *amphetamine-like psychostimulants*, or *antihypertensive agents* (medicines used for high blood pressure), as this may cause a rise in blood pressure largely because of interaction with pseudoephedrine HCl. The effects of a single dose of ADCO FLUPAIN on the blood pressure of these patients should be watched before giving further doses.
- ADCO FLUPAIN and furazolidone (an antibacterial drug) should not be taken together
- The effects of pseudoephedrine HCl in ADCO FLUPAIN are decreased by *antihypertensive medicines (guanethidine, reserpine, methyldopa*) and may be decreased by tricyclic antidepressants.
- The effects of *atropine* (medicine used to treat certain types of nerve agent and pesticide poisonings) and tricyclic antidepressants may be increased by the triprolidine HCl in ADCO FLUPAIN
- Triprolidine HCl in ADCO FLUPAIN may mask the warning symptoms of damage caused by *ototoxic drugs* (drugs that cause damage to the ear) and may affect the metabolism of drugs in the liver.

- Long term use of *anticonvulsants* and *oral steroid contraceptives* cause an increase in the first past metabolism or clearance rate and may prevent attainment of therapeutic levels. Reversal of the effect of *antihypertensive agents* may occur.
- Do not give together with *cardiac glycosides, quinidine*, and *tricyclic antidepressant* medicines.
- The depressant effects of triprolidine in ADCO FLUPAIN are increased by *alcohol, anaesthetics, hypnotics, sedatives, tricyclic antidepressants* and *phenothiazines*.
- *Monoamine oxidase inhibitors* may enhance the anticholinergic effects (dry mouth, throat and nose; constipation, heartburn; increased body temperature and flushed skin, pupil dilation and sensitivity to light, poor coordination and confusion; drowsiness, hallucinations and delirium) of triprolidine in ADCO FLUPAIN.
- ADCO FLUPAIN should be avoided with *cyclopropane, halothane* or other anaesthetics agents (medicine used to prevent pain and discomfort during surgery).
- The absorption of paracetamol may be increased by *metoclopramide (medicine used for vomiting).*
- Cholestyramine (medicine used to bind bile in the GI tract) reduces the absorption of paracetamol.
- Prolonged concurrent use of ADCO FLUPAIN with salicylates (e.g. aspirin) increases the risk of adverse kidney effects.
- If your child is taking *warfarin* or other blood thinning medicines (*anticoagulants*). ADCO FLUPAIN may increase the anticoagulant effect and there is an increased risk of bleeding if your child takes regular or high doses of paracetamol while on an oral anticoagulant.
- The risk of side effects with paracetamol may be increased in patients taking other medicines that may be harmful to the liver or medicines that can influence the functioning of the liver (i.e medicines used to treat seizures: *carbamazepine*, *phenobarbital, phenytoin, or primidone*).
- Excretion of paracetamol may be affected and plasma (blood) concentrations altered when taken together with *probenecid* (medicine used to treat gout).
- Use of ADCO FLUPAIN and certain antibacterials used for the treatment of tuberculosis (a disease affecting the lungs) such as *rifampicin* or *isoniazid* can cause toxic damage to the liver.
- Taking ADCO FLUPAIN together with certain antiviral medicines such as *zidovudine* can cause severe toxic damage to the liver. The antiviral effect of *interferon alfa* may be increased if taken with ADCO FLUPAIN.

ADCO FLUPAIN with food, drink and alcohol

ADCO FLUPAIN may be taken with or without food.

Do not drink alcohol while you are taking ADCO FLUPAIN.

Pregnancy, breastfeeding and fertility

Do not take this syrup during pregnancy or whilst breastfeeding. No fertility data available. If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking ADCO FLUPAIN.

Driving and using machines

The effects of ADCO FLUPAIN on your child's ability to concentrate may be impaired. It is not always possible to predict to what extent ADCO FLUPAIN may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which ADCO FLUPAIN affects them.

3. How to give ADCO FLUPAIN

Do not share medicines prescribed for you with any other person.

Always give ADCO FLUPAIN exactly according to instructions. You should check with a doctor or pharmacist if you are unsure.

The usual dose is:

Children 2 to 5 years: 5 ml three times a day.

Children 6 to 12 years: 5 ml - 10 ml three times a day.

Not for use in children under 2 years of age.

Consult your doctor if no relief is obtained with the recommended dosage.

DO NOT EXCEED THE RECOMMENDED DOSE

Do not use ADCO FLUPAIN for longer than 10 days without consulting a doctor.

Shake the bottle before use.

If you give more ADCO FLUPAIN than you should:

In the event of overdosage, consult your doctor or pharmacist. If neither is available, seek help at the nearest hospital or poison control centre immediately. Take this leaflet and the rest of the remaining syrup with you so the doctor will know what you have taken. Should your child or somebody else have taken an overdose of ADCO FLUPAIN, the following symptoms may be experienced (due to paracetamol overdose):
loss of appetite, nausea, vomiting, pale skin and stomach pain. These symptoms may be mild and do not reflect the potential seriousness of the overdosage which can result in liver damage or death. Treatment must be started within 24 hours in order to prevent this.

If you forget to use ADCO FLUPAIN

Use your next dose at your regular time.
Do not take a double dose to make up for forgotten individual doses.

4. Possible Side Effects

ADCO FLUPAIN can have side effects.

Not all side effects reported for ADCO FLUPAIN are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking ADCO FLUPAIN, please consult your health care provider for advice.

If any of the following happens, stop giving ADCO FLUPAIN and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Your child has an allergic reaction. The signs may include: shortness of breath, wheezing, difficulty breathing, rash, itching, hives on the skin, swelling of your lips, face or throat.
- Your child gets a headache, feels confused or has a seizure.
- Your child has mouth ulcers, cold sores and ulcers or soreness on their tongue.
- Your child has skin lumps or hives (raised, red or white, itchy patches of skin).
- Your child has blisters on their skin or inside their mouth, nose, vagina or bottom.
- The appearance of a rash or sunburn when they have been outside (even on a cloudy day).

- swelling of the eyelids, face, tongue or lips
- severe dizziness
- difficulty in breathing
- Serious skin reactions such as swelling, itching, red severe rash especially those covering your whole body (appearing as allergic wheals), stop giving ADCO FLUPAIN immediately and contact your doctor (see Section 2).
- Serious conditions affecting blood vessels in the brain known as posterior reversible encephalopathy syndrome (PRES) and reversible cerebral vasoconstriction syndrome (RCVS).

Stop using ADCO FLUPAIN immediately and seek urgent medical attention if you develop symptoms, that may be signs of posterior reversible encephalopathy syndrome (PRES) and reversible cerebral vasoconstriction syndrome (RCVS). These include:

- severe headache with a sudden onset
- feeling sick
- vomiting
- confusion
- seizures changes in vision

Tell your doctor if you notice any of the following:

Frequent	**Less frequent**	**Unknown**
Restlessness, difficulty sleeping, nervousness, CNS depression ranging from slight drowsiness to deep sleep, dizziness, incoordination, headache, psychomotor impairment, blurred vision, thickened	Thrombocytopenia (low levels of blood platelets which can lead to bleeding and bruising), agranulocytosis (very low level of a type of white blood cell which are important for fighting off infection), leucopenia (low levels of white blood cells), neutropenia (low levels of neutrophils, a type of white blood	anaphylaxis (sudden, severe allergic reaction with breathing difficulty, swelling, light-headedness, fast heartbeat, sweating and loss of consciousness), photosensitivity, drug-induced hypersensitivity syndrome (DIHS) (hypersensitivity reactions characterised by an itchy rash, shortness of breath, and low blood

respiratory tract secretions, dry mouth, constipation, increased gastric reflux, nausea, urinary retention	cell that fights infection), pancytopenia (low levels of blood cells) and anaemia (low levels of red blood cells), Allergic reactions, hypersensitivity with other similar drugs, hallucination, confusional state, depression, seizures, muscle pain, tremor, rapid heartbeat, dizziness, fainting, reflex slow heart rhythm, abnormal heart rate, cardiac arrest, and shortness of breath, sweating, low blood pressure, excessive and prolonged contraction of the airway muscles causing breathing difficulty, vomiting, diarrhoea, abdominal pain, inflammation of the pancreas & liver, skin rash, dermatitis, and other allergic reactions, Renal colic, renal failure and Urinary tract infection, difficulty in urinating	pressure), hair loss, metabolic acidosis, reduced appetite, altered metabolism, disturbances of glucose metabolism, anxiety, paraesthesia (sensations like numbness, tingling, pins and needles), fear, irritability, psychotic state, agitation, delusion, extreme happy mood, degeneration of the eye nerve, hearing loss, ringing in the ears, Possible increase in the risk of hypertension, heart pain, fluid around the heart, fluid build up in the lungs, dry throat, nasal dryness, nosebleed, increased saliva, loss of kidney function, painful urination, weakness, fatigue, high temperatures, Fixed drug eruption (cutaneous adverse drug effect in the form of recurrent lesions at the same site after re-exposure to the offending agent), stroke, posterior reversible encephalopathy syndrome (PRES) (brain swelling with usually temporary effects such as headache, changes in vision, reduced consciousness and seizures) / reversible cerebral vasoconstriction syndrome (RCVS) (a rare condition characterized by sudden and extremely painful thunderclap headaches), renal colic (abdominal pain caused by kidney stones)

Not all side effects reported for this medicine are included in this leaflet. Should your child's general health worsen or if your child experiences any untoward effects while taking this medicine, please consult your doctor, pharmacist or other health care professional for advice.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse.

You can report side effects to the Adcock Ingram Pharmacovigilance department by e- mail to Adcock.Aereports@adcock.com, fax to +27 86 553 0128 or call 011 635 0134. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.

By reporting side effects, you can help provide more information on the safety of ADCO FLUPAIN.

5. How to store ADCO FLUPAIN

Keep all medicines out of the reach and sight of children.

Store in a well-closed container, at or below 25 °C.

Protect from light.

Store in the original container in a cool place. Keep the container tightly closed and do not store the product in bathrooms in order to protect from moisture.

Do not use after the expiry date on the label.

Do not dispose of unused medicines in drains or sewerage systems.

6. Contents of the pack and other information

What ADCO FLUPAIN contains:

Each 5 ml contains:	
Triprolidine hydrochloride	0,625 mg
Pseudoephedrine hydrochloride	15 mg

Paracetamol	125 mg

The other ingredients are citric acid anhydrous [E330], colour raspberry red H1277 Bba², flavour raspberry 203580², glycerol [E422], methylparaben [E218], polyvinylpyrrolidone K25, propylene glycol, propylparaben [E216], saccharin sodium [E954], sodium citrate dihydrate [E331] sorbitol 70 % solution [E420], xanthan gum, ethanol 96 % and purified water.

What ADCO FLUPAIN looks like and contents of the pack

A clear, pink to red syrup with a raspberry odour.

Amber glass bottles containing 50 ml, 100 ml, 200 ml and amber PET bottle containing 100 ml with child proof screw on cap.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

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