PACKAGE LEAFLET

Package leaflet: Information for the user

Tachifenekid 32 mg/ml + 9.6 mg/ml oral suspension

Paracetamol/Ibuprofen

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 or pharmacist.
- 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 or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Tachifenekid is and what it is used for

Tachifenekid contains paracetamol and ibuprofen.
Paracetamol works to stop the pain messages from getting through to the brain.
Ibuprofen belongs to a group of medicines called non-steroidal anti-inflammatory drugs (or NSAIDs). It relieves pain and reduces inflammation (swelling, redness or soreness).

Tachifenekid is used for short-term management of mild to moderate acute pain which is not considered to be relieved by paracetamol or ibuprofen (alone) in children 2-12 years of age.

Ask your doctor or pharmacist if you have any questions about this medicine.
You must talk to a doctor if your child does not feel better or if they feel worse after 3 days.

2. What you need to know before you take Tachifenekid

Excipients with known effect:
1. Maltitol liquid (E965) 250 mg/ml
2. Propylene glycol (E1520) 9.6 mg/ml
3. Sodium benzoate (E211) 1 mg/ml
4. Sodium 1.23 mg/ml
5. Glycerol (E422) 150 mg/ml

Each 1ml of oral solution contains 9.6 mg propylene glycol and 1mg sodium benzoate.

- **Do not use Tachifenekid:** if your child is allergic to the active substance(s) or any of the other ingredients of this medicine (listed in section 6);
- if your child is (or has previously) bled from the rectum (back passage), has black sticky bowel motions (stools) or bloody diarrhoea;

- if your child has a peptic ulcer (i.e. stomach or duodenal ulcer), a recent history of one, or has had peptic ulcers before;
- with any other medicines containing paracetamol or ibuprofen
- if your child has severe heart failure, hepatic failure or renal failure
- if your child has cerebrovascular or other active bleeding
- if your child has blood-formation disturbances
- if your child has asthma, urticaria or allergic-type reactions after taking acetylsalicylic acid or other NSAIDs

If you are an adult, in addition to the above, do not use Tachifenekid if you:
- regularly drink large quantities of alcohol
- are in the last three months of pregnancy

Warnings and precautions
What you need to know before you take [product]
Signs of an allergic reaction to this medicine, including breathing problems, swelling of the face and neck region (angioedema), chest pain have been reported with ibuprofen. Stop immediately [product name] and contact immediately your doctor or medical emergencies if you notice any of these signs.

Talk to your doctor or pharmacist before taking Tachifenekid

Anti-inflammatory/pain-killer medicines like ibuprofen may be associated with a small increased risk of heart attack or stroke, particularly when used at high doses. Do not exceed the recommended dose or duration of treatment.

There is a risk of renal (kidney) impairment in dehydrated children. You should talk to your doctor or pharmacist before giving your child Tachifenekid if your child:
- has high blood pressure, kidney or liver problems;
- has asthma or diabetes;
- has lupus or a mixed connective tissue disease;
- has a chronic inflammatory intestinal disease such as ulcerative colitis, Crohn's disease of gastrointestinal bleeding;
- has chicken pox
- has liver disease, hepatitis, kidney disease or difficulty urinating;
- has allergies to any other medicines contain acetylsalicylic acid or other NSAID medicines or any other substances listed at the end of this leaflet;
- currently has an infection;
- is scheduled to have surgery;
- has or has had other medical conditions including:
    - heartburn, indigestion, stomach ulcer or any other stomach problems;
    - vomiting blood or bleeding from back passage;
    - severe skin reactions such as Stevens-Johnson syndrome;
    - asthma;
    - vision problems;
    - tendency to bleed or other blood problems;
    - bowel or intestinal problems such as ulcerative colitis or Crohn's Disease
    - swelling of ankles or feet;
    - diarrhoea.
    - inherited genetic or acquired disorder of certain enzymes that manifest with either neurological
    - complications or skin problems or occasionally both i.e. porphyria
    - smallpox
    - autoimmune disease such as Lupus erythematosus
-

This product is intended for children aged between 2 and 12 years. If you are an adult taking this product, all the above statements apply and so do the following additional warnings:
Tell your doctor or pharmacist if:
- you are a drug user;
- you are pregnant or intend to become pregnant;
- you are breastfeeding or plan to breastfeed.

During treatment with Tachifenekid, tell your doctor straight away if:
If you have severe illnesses, including severe renal impairment or sepsis (when bacteria and their toxins circulate in the blood leading to organ damage), or you suffer from malnutrition, chronic alcoholism or if you are also taking flucloxacillin (an antibiotic). A serious condition called metabolic acidosis (a blood and fluid abnormality) has been reported in patients in these situations when paracetamol is used at regular doses for a prolonged period or when paracetamol is taken together with flucloxacillin. Symptoms of metabolic acidosis may include: serious breathing difficulties with deep rapid breathing, drowsiness, feeling sick (nausea) and being sick (vomiting).

Do not drink alcoholic beverages when taking this medication. Combining alcohol with Tachifenekid may lead to liver damage.
The product belongs to a group of medicines (NSAIDs) which may impair the fertility in women. This effect is reversible on stopping the medicine.

Take special care with Tachifenekid:

Skin reactions
Serious skin reactions including exfoliative dermatitis, erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis, drug reaction with eosinophilia and systemic symptoms (DRESS), acute generalized exanthematous pustulosis (AGEP) have been reported in association with <ibuprofen> treatment. Stop using Tachifenekid and seek medical attention immediately if you notice any of the symptoms related to these serious skin reactions described in section 4.

Other medicines and Tachifenekid
Tell your doctor or pharmacist if you or your child are taking, have recently taken or might take any other medicines.

Tachifenekid may affect or be affected by some other medicines. For example:
- medicines that are anti-coagulants (i.e. thin blood/prevent clotting e.g. aspirin/acetylsalicylic acid, warfarin, ticlopidine)
- medicines to treat epilepsy or fits
- chloramphenicol, an antibiotic used to treat ear and eye infections
- probenecid, a medicine used to treat gout
- zidovudine, a medicine used to treat HIV (the virus that causes acquired immunodeficiency disease)
- medicines used to treat tuberculosis such as isoniazid
- acetylsalicylic acid, salicylates or other NSAID medicines
- medicines that reduce high blood pressure (ACE-inhibitors such as captopril, beta-blockers such as atenolol medicines, angiotensin-II receptor antagonists such as losartan)
- diuretics, also called fluid tablets
- lithium, a medicine used to treat some types of depression
- methotrexate, a medicine used to treat arthritis and some types of cancer
- corticosteroids, such as prednisone, cortisone
- metoclopramide, propantheline
- tacrolimus or ciclosporin, immunosuppressive drugs used after organ transplant
- sulphonylureas, a medicine used to treat diabetes
- some antibiotics (such as quinolone antibiotics)
- flucloxacillin (antibiotic), due to a serious risk of blood and fluid abnormality (called metabolic acidosis) that must have urgent treatment (see section 2).

These medicines may be affected by Tachifenekid or may affect how well Tachifenekid works. You may need different amounts of your medicines, or you may need to take different medicines.

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

Your doctor and pharmacist will have more information on these and other medicines to be careful with or avoid while taking this medicine.

Pregnancy, breast-feeding and fertility
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.
Do not take this medicine during the last 3 months of your pregnancy.
It can cause kidney and heart problems in your unborn baby. It may affect your and your baby's tendency to bleed and cause labour to be later or longer than expected.
You should not take this product during the first 6 months of pregnancy unless absolutely necessary and advised by your doctor. If you need treatment during this period or while you are trying to get pregnant, the lowest dose for the shortest time possible should be used. If taken for more than a few days from 20 weeks of pregnancy onward, this product can cause kidney problems in your unborn baby that may lead to low levels of amniotic fluid that surrounds the baby (oligohydramnios) or narrowing of a blood vessel (ductus arteriosus) in the heart of the baby. If you need treatment for longer than a few days, your doctor may recommend additional monitoring.
This product may impair female fertility and is not recommended in women attempting to conceive.

Driving and using machines
Be careful driving or operating machines until you know how Tachifenekid affects you.

Tachifenekid contains maltitol liquid sodium benzoate, sodium and propylene glycol

- Maltitol liquid: if you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.
- Sodium benzoate: this medicine contains 1 mg of sodium benzoate in each 1 ml.
- Sodium: Tachifenekid contains up to 38 mg sodium (main component of cooking/table salt) per dose. This is equivalent to 1.9% of the recommended maximum daily dietary intake of sodium for an adult.
- Propylene glycol: this medicine contains approximately 9.6 mg propylene glycol in each ml which is equivalent to up to 16 mg/kg/day.

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

3. How to use Tachifenekid

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist or if you are not sure.

In children up to 10 years of age it is essential to respect the posology on the basis of body weight and not age, which is approximate and reported only for information.

Body weight	Age (approximate)	Dose (mL)
from 12 kg	2 years	4.5
from 14 kg	3 years	5.5
from 16 kg	4 years	6

from 18 kg	5 years	7
from 20 kg	6 years	7.5
from 22 kg	7 years	8.5
from 25 kg	8 years	9.5
from 28 kg	9 years	10.5
from 31 kg	10 years	11.5
33-40 kg*	11-12 years	12.5

* In children over 10 years of age, the relationship between weight and age is no longer homogeneous due to pubertal development which has a different impact on body weight depending on the gender and individual characteristics.

Doses should be given every 4-6 hours as necessary, with no more than 4 doses in 24 hours.

For adults or elderly taking this product, consult with your doctor to determine what dose you should take.

Use the lowest effective dose for the shortest time necessary to relieve symptoms. Tachifenekid is for short-term use only. You should consult a doctor if the symptoms persist or worsen after 3 days.

If your doctor prescribes a different dose, follow directions given by your doctor.

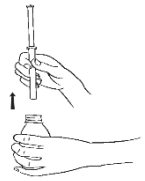
Directions for using the syringe:

1. Shake the bottle for at least 10 seconds before use.

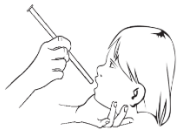
2. Push the syringe firmly into the plug (hole) in the neck of the bottle.

3. To fill the syringe, turn the bottle upside down. Whilst holding the syringe in place, gently pull the plunger down drawing the medicine to the correct mark on the syringe.

4. Turn the bottle the right way up, and then gently twist the syringe to remove from the bottle plug.



5. Place the end of the syringe into the child's mouth, normally to the side of the mouth between the gums and cheek. Press the plunger down to slowly and gently release the medicine.



6. If the table above advises you to give more than 5 mL of the medicine, repeat steps 2 to 5 to give your child the correct amount of medicine.

7. After use replace the cap on the top of the bottle tightly. Store all medicines out of the sight and reach of children.
8. Wash the syringe in warm water and allow to dry.

Do not mix this medicine with other food or drinks.

If you use more Tachifenekid than you should

Talk to a doctor at once if you or your child takes by accident too much of this medicine even if they feel well. This is because too much paracetamol can cause delayed, serious liver damage. Immediately telephone your doctor for advice or go to Accident and Emergency at the nearest hospital, if you think that your child or anyone else may have taken too much Tachifenekid. Do this even if there are no signs of discomfort or poisoning. Your child may need urgent medical attention.

The symptoms of overdose can include nausea, stomach pain, vomiting (may be blood streaked), gastrointestinal bleeding (see also part 4 below), diarrhoea, headache, ringing in the ears, confusion and shaky eye movement. Also may occur agitation, somnolence, disorientation or coma may occur. Occasionally patients develop convulsions. At high doses, drowsiness, chest pain, palpitations, loss of consciousness, convulsions (mainly in children), weakness and dizziness, blood in urine, low levels of potassium in your blood, cold body feeling, and breathing problems have been reported. Further, the prothrombin time/INR may be prolonged, probably due to interference with the actions of circulating clotting factors. Acute renal failure and liver damage may occur. Exacerbation of asthma is possible in asthmatics. Furthermore, there may be low blood pressure and reduced breathing.

If you forget to give your child Tachifenekid

If it is almost time for their next dose, skip the missed dose and give their next dose when you are meant to. Otherwise, give it as soon as you remember, and then go back to giving the suspension as you would normally.

Do not give a double dose to make up for a forgotten dose.

If you are not sure whether to skip the dose, talk to your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.
If any side effects become serious or if you notice any side effects that are not listed in this leaflet, please tell your doctor or pharmacist.

If any of these serious side effects happen, stop using Tachifenekid and tell your doctor immediately or go to the emergency room at your nearest hospital:

- reddish non-elevated, target-like or circular patches on the trunk, often with central blisters, skin peeling, ulcers of mouth, throat, nose, genitals and eyes. These serious skin rashes can be preceded by fever and flu-like symptoms [exfoliative dermatitis, erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis].
- widespread rash, high body temperature and enlarged lymph nodes (DRESS syndrome).
- a red, scaly widespread rash with bumps under the skin and blisters accompanied by fever. The symptoms usually appear at the initiation of treatment (acute generalised exanthematous pustulosis).

Common:

- vomiting blood or material that looks like coffee grounds;
- bleeding from the back passage, black sticky bowel motions (stools) or bloody diarrhoea;
- swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing;

Very rare:

- asthma, wheezing, shortness of breath;
- sudden or severe itching, skin rash, hives;
- severe rash with blisters and bleeding in the lips, eyes, mouth, nose and genitals (Steven Johnson Syndrome). Very rare cases of serious skin reactions have been reported;
- worsening of existing severe skin infections (you may notice a rash, blistering and discolouration of the skin, fever, drowsiness, diarrhoea and sickness), or worsening of other infections including chicken pox or shingles or severe infection with destruction (necrosis) of subcutaneous tissue and muscle, blistering and peeling of the skin;
- fever, generally feeling unwell, nausea, stomach ache, headache and stiff neck.

Other possible side effects are:

Common (may affect up to 1 in 10 people)*:*

- nausea or vomiting;
- loss of appetite;
- heartburn or pain the upper part of your stomach;
- cramps, wind, constipation or diarrhoea, slight gastrointestinal blood loss;
- skin rashes, itching of the skin;
- headache;
- dizziness;
- feeling of being nervous;
- ringing or buzzing in the ears;
- unusual weight gain, swelling and fluid retention, swelling of ankles or legs (oedema).

Uncommon (may affect up to 1 in 100 people):

- decrease in red blood cells, nose bleed and heavier periods (menstrual bleeding);
- allergic reactions – skin rash, tiredness, joint pain (e.g. serum sickness, lupus erythematosus syndrome, Henoch-Schönlein vasculitis, angioedema);
- enlargement of breast tissue in men; low blood sugar levels;
- sleeplessness;
- change in mood, for example depression, confusion, nervousness
- eye problems such as blurred vision (reversible), sore red eyes, itching;
- thickened mucus;
- Wheezing from disrupted airflow in children during tonsillectomy surgery;
- Low blood oxygen levels;
- severe pain or tenderness in the stomach; peptic/gastrointestinal ulcer;
- Bowel inflammation and worsening of inflammation of the colon (colitis) and digestive tract (Crohn's disease) and complications of diverticula of the large bowel (perforation or fistula);
- inability to completely empty the bladder (urinary retention);
- abnormal laboratory test results (blood, liver and kidney enzyme test results);
- post-operative bleeding after tonsillectomy surgery.

Rare (may affect up to 1 in 1,000 people):

- tingling of the hands and feet;
- abnormal dreams, seeing things (hallucinations);
- damage of the kidney tissue (particularly in long-term use);
- high level of uric acid in your blood (hyperuricemia).

Very rare (may affect up to 1 in 10,000 people):

- low potassium levels – weakness, fatigue, muscle cramps (hypokalaemia);
- signs of anaemia, such as tiredness, headaches, being short of breath, and looking pale;
- bleeding or bruising more easily than normal, reddish or purplish blotches under the skin;

- severe or persistent headache;
- spinning sensation (vertigo);
- fast or irregular heartbeats, also called palpitations;
- increase in blood pressure and possible heart problems;
- inflammation of the oesophagus;
- yellowing of the skin and /or eyes, also called jaundice;
- liver damage (particularly in long term use);
- loss of hair;
- increase in sweating;
- signs of frequent or worrying infections such as fever, severe chills, sore throat or mouth ulcers.

Not known (frequency cannot be estimated from the available data):

- a severe skin reaction known as DRESS syndrome can occur. Symptoms of DRESS include: skin rash, fever, swelling of lymph nodes and an increase of eosinophils (a type of white blood cells).
- A red, scaly widespread rash with bumps under the skin and blisters mainly localized on the skin folds, trunk, and upper extremities accompanied by fever at the initiation of treatment (acute generalised exanthematous pustulosis). Stop using Tachifenekid if you develop these symptoms and seek medical attention immediately. See also section 2.
- Chest pain, which can be a sign of a potentially serious allergic reaction called Kounis syndrome
- A serious condition that can make blood more acidic (called metabolic acidosis), in patients with severe illness using paracetamol (see section 2).

The above list includes serious side effects that may require medical attention. Serious side effects are rare for low doses of this medicine and when used for a short period of time.

Reporting of side effects

If your child gets any side effects talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via ADR Reporting Website: www.medicinesauthority.gov.mt/adrportal. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Tachifenekid

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

Store below 25˚C.
In-use shelf life is 3 months, when stored at or below 25°C.

Do not use this medicine after the expiry date which is stated on the carton and on the bottle after EXP. The expiry date refers to the last day of that month.

Do not use this medicine if you notice packaging is torn or shows signs of tampering.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Tachifenekid contains
The active substances are: paracetamol 32 mg and ibuprofen 9.6 mg per 1 mL of product.

The other ingredients are: citric acid monohydrate (E330), glycerol (E422), maltitol liquid (E965), Polysorbate 80 (E433), sodium benzoate (E211), sodium citrate dihydrate (E331), sucralose (E955), Vivapur MCG 591P (microcrystalline cellulose and carmellose sodium), xanthan gum (E415), masking flavor, strawberry flavor, sweet flavor, vanilla flavor, and carmine (E120).

What Tachifenekid looks like and contents of the pack

Tachifenekid is a viscous pink suspension.

Each pack contains a 100 mL or 200 mL bottle with a child-resistant closure and a measuring syringe of 5 mL to be used as a dosage delivery device

Marketing Authorisation Holder

Aziende Chimiche Riunite Angelini Francesco – A.C.R.A.F. S.p.A
Viale Amelia 70
00181 Roma.

Manufacturer

SAG Manufacturing S.L.U. Carretera N-I, Km 36, San Agustin de Guadalix, 28750 Madrid, Spain.

This medicinal product is authorised in the Member States of the EEA under the following names:

Malta: Tachifenekid 32 mg/ml + 9,6 mg/ml oral suspension
Italia: Tachifenekid

This leaflet was last revised in December 2024.