

Package leaflet: Information for the user

Buplex Junior 100 mg/5 ml oral suspension

Ibuprofen

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

Always use this medicine exactly as described in this leaflet or as your doctor, pharmacist or nurse has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- The leaflet is written in terms of giving this medicine to your child, but if you are an adult who is intending to take this medicine yourself the information in this leaflet will apply to you as well.
- If your child gets any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if your child does not feel better or feels worse
 - after 24 hours if your child is aged under 6 months
 - after 3 days if your child is aged over 6 months

What is in this leaflet

1. What Buplex Junior is and what it is used for
2. What you need to know before giving Buplex Junior to your child
3. How to use Buplex Junior
4. Possible side effects
5. How to store Buplex Junior
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1. What Buplex Junior is and what it is used for

Buplex Junior contains ibuprofen which belongs to a group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs) which act to relieve pain, swelling (inflammation) and reduce fever.

Buplex Junior is for use in children from 3 months of age who weigh more than 5 kg.

It can be used for the relief of mild to moderate pain such as sore throat, teething pain, toothache, ear ache, headache, minor aches and sprains. It can also be used to relieve the symptoms of colds and flu and to reduce fever, including fever after vaccination at 3 months of age.

2. What you need to know before giving Buplex Junior to your child

This medicine is suitable for the majority of people but certain people should not use it. Talk to your doctor or pharmacist if you are at all unsure.

Do not give this medicine to your child if:

- they are allergic to ibuprofen or any of the other ingredients of this medicine (listed in section 6)
- they have ever had a reaction (e.g. asthma, runny nose, rash, swelling of the face, tongue, lips or throat) after taking ibuprofen, acetylsalicylic acid (aspirin) or other non-steroidal-anti-inflammatory (NSAID) medicines
- they weigh less than 5 kg or are under 3 months of age

- they are taking any other anti-inflammatory (NSAID) medicines, or acetylsalicylic acid (aspirin) with a daily dose above 75 mg (acetylsalicylic acid should not generally be given to children under 16, but doctors may occasionally prescribe it)
- they have a stomach ulcer, perforation or bleeding, or they have had one twice or more in the past
- they have had perforation or a bleeding ulcer after taking a non-steroidal anti-inflammatory (NSAID) medicine (your child may have been sick and it contained blood or dark particles that look like coffee grounds, passed blood in their stools or passed black tarry stools)
- they have severe kidney, heart or liver failure
- they have a condition which increases their tendency to bleeding

Warnings and precautions

Talk to your doctor, pharmacist or nurse before giving Buplex Junior.

This is especially important if:

- your child has asthma, a history of asthma or other allergic disease
- your child has or has had kidney, liver or heart problems
- your child is dehydrated as there is a risk of kidney problems
- your child has connective tissue disorders such as SLE (Systemic Lupus Erythematosus)
- your child suffers from chronic inflammatory bowel disease such as Crohn's disease or ulcerative colitis.
- your child has chickenpox

Like other anti-inflammatory drugs, Buplex Junior can mask signs of infection.

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.

You should discuss your child's treatment with your doctor or pharmacist before giving Buplex Junior if your child:

- has heart problems including heart failure, angina (chest pain), or if they 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").
- has high blood pressure, diabetes, high cholesterol, or has a family history of heart disease or stroke.

Other medicines and Buplex Junior

Tell your doctor or pharmacist if your child is taking, has recently taken or might take any other medicines.

- Buplex Junior may affect or be affected by some other medicines. For example: Other medicines containing ibuprofen or other NSAIDs, including those you can buy over the counter
- Acetylsalicylic acid (aspirin)
- Medicines that are anti-coagulants (i.e. thin blood/prevent clotting e.g. aspirin/acetylsalicylic acid, warfarin, ticlopidine)
- Antiplatelet drugs (e.g. dipyridamole, clopidogrel)
- Mifepristone (for termination of pregnancy)
- Zidovudine (for HIV infection)
- Medicines known as sulfonylureas such as glibenclamide (used to treat diabetes)
- Methotrexate (for psoriasis, arthritis and types of cancer)
- Cardiac glycosides (e.g. digoxin – used to treat particular heart problems)
- Diuretics ('water tablets')
- Medicines that reduce high blood pressure (ACE-inhibitors such as captopril, beta-blockers such as atenolol medicines, angiotensin-II receptor antagonists such as losartan)

- Corticosteroids (an anti-inflammatory drug)
- SSRI antidepressant drugs (for depression)
- Aminoglycoside antibiotics (for infection)
- Lithium (for mood disorders)
- Ciclosporin or tacrolimus (to prevent organ rejection after transplant)
- Cholestyramine (used to lower cholesterol)
- Voriconazole or fluconazole (types of anti-fungal drugs)

Seek the advice of your doctor or pharmacist if any of the above apply.

Some other medicines may also affect or be affected by the treatment of Buplex Junior. You should therefore always seek the advice of your doctor or pharmacist before your child uses Buplex Junior with other medicines.

If you are not sure what types of medicines your child is taking, show the medicine to the doctor or pharmacist.

Buplex Junior 100 mg/5 ml oral suspension contains maltitol liquid and sodium

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

Maltitol liquid may have a mild laxative effect.

Each 5 ml spoonful contains 2 g of maltitol liquid. This provides 4.6 kcal per 5 ml spoonful.

This medicinal product contains 7.37 mg of sodium in each 5 ml dose. To be taken into consideration by patients on a controlled sodium diet.

If you are an adult intending to take this medicine:

All the information in this leaflet applies to you as well.

In addition:

- If you are elderly you may be more likely to have some of the possible side effects listed later in the leaflet. Talk to your doctor before taking this medicine.
- If you are a smoker, you should discuss your treatment with your doctor or pharmacist.

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.

Pregnancy

During the first 6 months of pregnancy you should only take this product if advised to do so by your doctor.

DO NOT take Buplex Junior if you are in the last 3 months of your pregnancy

Breast-feeding

In limited studies, ibuprofen appears in the breast milk in very low concentration and is unlikely to affect the breast-fed infant adversely.

Fertility

Ibuprofen belongs to a group of medicines (NSAIDs) which may impair fertility in women. This effect is reversible on stopping the medicine. It is unlikely that this medicine, used occasionally, will affect your chances of becoming pregnant, however, tell your doctor before taking this medicine if you have problems becoming pregnant.

Driving and using machines

Since side effects such as dizziness and visual disturbances may be experienced, the ability to drive a car or operate machinery may be impaired.

3. How to use Buplex Junior

Always give this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Always shake the bottle thoroughly before use.

Always use the syringe supplied with the pack. The syringe can be used to measure 2.5 ml or 5 ml by drawing the liquid to the correct mark on the syringe.

The recommended dose is:

Fever caused by immunisation		
Your child's weight (and age)	How much?	How often?
Over 5 kg (3 months and over)	2.5 ml	Up to twice in 24 hours*
<p>* If necessary, the second dose should be given 6 hours after the first dose.</p> <ul style="list-style-type: none"> • Do not give more than 2 doses in a 24 hour period. • Do not give any more medicine after second 2.5 ml. See a doctor if fever continues. 		

Fever, Pain and Symptoms of Cold and Flu		
Your child's weight (and age)	How much?	How often in 24 hours?***
Over 5 kg (3 - 6 months)	2.5 ml	3 times Do not use for more than 24 hours
7 – 10 kg (6 - 12 months)	2.5 ml	3 or 4 times
10 – 15 kg (1 - 3 years)	5 ml	3 times
15 – 20 kg (4 - 6 years)	7.5 ml (5 ml + 2.5 ml)	3 times
20 – 30 kg (7 - 9 years)	10 ml (5 ml + 5 ml)	3 times

30 – 40 kg (10 - 12 years)	15 ml (5 ml + 5 ml + 5 ml)	3 times
** Doses should be given every 6 - 8 hours. Leave at least 6 hours between doses.		

Do not give to a child under 3 months of age, unless advised to do so by your doctor.

For **Short-term use only**

- Do not give to babies aged 3-6 months for longer than 24 hours.
- Do not give to children aged 6 months or over for longer than 3 days

Consult your doctor if symptoms worsen or persist

Give the lowest amount for the shortest possible time to relieve the symptoms.

Do not give more than the amount recommended above.

Directions for using the syringe:

1. Shake the bottle thoroughly 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 (2.5 ml or 5 ml) 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.

After use replace the cap on the top of the bottle tightly. Store all medicines out of the sight and reach of children.

Wash the syringe in warm water and allow to dry.

If you use more Buplex Junior than you should

If you accidentally give or take more Buplex Junior than the recommended dose, contact a doctor straight away.

If you forget to use Buplex Junior

If you forget a dose, give then next dose when needed, provided that the last dose was taken at least 6 hours ago. Do not take a double dose to make up for a forgotten dose.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Medicines such as Buplex Junior may be associated with a small increased risk of heart attack (myocardial infarction) or stroke.

Water retention (oedema), high blood pressure and heart failure have been reported in association with NSAIDs.

If your child experiences any of the following serious side effects, stop giving this medicine and tell a doctor immediately:

Very common (may affect more than 1 in 10 users):

- Unexplained stomach pain, indigestion, heartburn or nausea

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

- Allergic reactions such as itchy, red, raised skin rash, unexplained wheezing (asthma) and feeling faint or dizzy
- Kidney failure (your child may pass more or less urine, have blood in the urine or cloudy urine, or feel breathless, very tired or weak, have no appetite, or have swollen ankles)

Rare (may affect up to 1 in 1000 users):

- Unexplained vomiting
- Joint pain, skin rashes and fever (these may be signs of an autoimmune condition called lupus erythematosus syndrome)

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

- Severe stomach pain, which may be a sign of intestinal perforation
- Signs of intestinal bleeding such as:
 - Passing blood in their stools or passing black tarry stools
 - Vomiting blood or dark particles that look like coffee grounds
- Severe allergic reactions. Symptoms could be swelling of the face, tongue, neck or throat, difficulty breathing, fast heart rate, feeling faint or dizzy or collapse
- Difficulty breathing
- Severe allergic skin reactions which may include peeling, blistering and lesions of the skin
- Worsening of existing severe skin infections (you may notice a rash, blistering and discolouration of the skin, fever, drowsiness, diarrhoea and sickness)
- Symptoms of meningitis such as stiff neck, fever, disorientation. Patients with existing autoimmune disorders such as systemic lupus erythematosus or mixed connective tissue disease seem to be at more risk
- Swellings or ulcers of the stomach
- Yellowing of the skin or eyes, pale stools or upper abdominal pain (these may be signs of liver problems)
- Tiredness or severe exhaustion, unusual bruising or unexplained bleeding and an increase in the number of infections that they get (e.g. sore throats, mouth ulcers, flu-like symptoms including fever). This could be caused by changes in the blood
- Kidney damage

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

- Severe skin infections and complications of the soft tissue during a chicken pox or shingles infection
- Heart failure (your child may be tired, have difficulty breathing or swollen legs)

Other side effects which may occur are:

Common (may affect up to 1 in 10 users):

- Gastrointestinal ulcers
- Headache
- Dizziness

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

- Diarrhoea, constipation and wind. Tell your doctor if these last for more than a few days or become troublesome
- Visual disturbances

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

- Worsening of colitis or Crohn's disease
- Swellings or ulcers of the mouth lining
- High blood pressure

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

- Fluid retention, which may cause swelling of the limbs
- A small increased risk of heart attack or stroke is possible if a high dose of ibuprofen is taken for a long time. This is unlikely at the dose level given to children

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRC 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 Buplex Junior

This medicine does not require any special storage conditions.
Shelf life after first opening the bottle: 6 months

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

Shake well before use.

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

Do not throw away any medicines via wastewater. 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 Buplex Junior contains

- The active substance is ibuprofen.
- 5 ml of oral suspension contains 100 mg of ibuprofen.
- The other ingredients are: sodium benzoate (E211), citric acid anhydrous, maltitol liquid, xanthan gum, hypromellose, glycerol, sodium chloride, polysorbate 80, sodium cyclamate, acesulfame potassium, sucralose, orange flavour ('Orange Juice 055604 TEU containing flavouring components (flavouring preparations, flavouring substances, natural flavoring substances), alpha-tocopherol (E307), benzyl alcohol), vanillin, purified water.

What Buplex Junior looks like and contents of the pack

Buplex Junior oral suspension is a white to almost white suspension with orange-vanilla flavour.

Buplex Junior oral suspension is supplied in an amber glass bottle containing 60 ml, 100 ml or 200 ml, or an amber plastic bottle containing 100 ml. The bottle is closed with a child-resistant plastic screw cap. Each pack also contains a plastic oral dosing syringe.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Actavis Group PTC ehf.,
Reykjavíkurvegi 76-78,
220 Hafnarfjörður
Iceland

Manufacturer

Balkanpharma Troyan AD, Bulgaria
1, Krayrechna Str., Troyan, 5600, Bulgaria

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

Bulgaria	Ibudolor Kids
Cyprus	Febralen
Iceland	Íbúfen
Ireland	Buplex Junior 100 mg / 5ml oral suspension
Norway	Ipandin
Poland	Ifenin dla dzieci
Romania	Adagin pentru copii 100mg/5 ml soluție orală
Sweden	Ipandin
United Kingdom	Ibuprofen 100mg/5ml Oral Suspension

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