

# BRUFEN®

## Paediatric Syrup

100 mg/5 ml ibuprofen

**Name of the medicinal product**  
Brufen® Paediatric Syrup

**Qualitative and quantitative composition**  
Ibuprofen BP 100 mg/5 ml

**Pharmaceutical form**  
An orange-coloured, orange-flavoured, syrupy suspension.

**Clinical particulars**  
**Therapeutic indications**

Brufen Syrup is indicated for its analgesic and anti-inflammatory effects in the treatment of rheumatoid arthritis (including juvenile rheumatoid arthritis or Still's disease), ankylosing spondylitis, osteoarthritis and other non-rheumatoid (seronegative) arthropathies. In the treatment of non-articular rheumatic conditions, Brufen Syrup is indicated in peri-articular conditions such as frozen shoulder, capsulitis, bursitis, tenosynovitis and low back pain; Brufen Syrup can also be used in soft-tissue injuries such as sprains and strains. Brufen Syrup is also indicated for its analgesic effect in the relief of mild to moderate pain such as dysmenorrhoea, dental and post-operative pain and for symptomatic relief of headache including migraine headache. Brufen Syrup is indicated in short-term use for the treatment of pyrexia in children over three months of age.

**Posology and method of administration**

Undesirable effects may be minimised by using the lowest effective dose for the shortest duration necessary to control symptoms. Adults and children over 12 years of age: The recommended dosage of Brufen is 1200-1800 mg daily in divided doses. Some patients can be maintained on 600-1200 mg daily. Total daily dose should not exceed 2400 mg. Children and infants: The daily dosage of Brufen is 20-30 mg/kg of bodyweight in divided doses. This can be achieved as follows: 3-6 months: One 2.5 ml spoonful (50 mg) up to three times a day. 6-12 months: One 2.5 ml spoonful (50 mg) three times a day. 1-2 years: One 2.5 ml spoonful (50 mg) three to four times a day. 2-7 years: One 5 ml spoonful (100 mg) three to four times a day. 8-12 years: Two 5 ml spoonfuls (200 mg) three to four times a day. Not recommended for children weighing less than 5 kg. In juvenile rheumatoid arthritis, up to 40 mg/kg of bodyweight daily in divided doses may be taken. In children weighing less than 30 kg, the total daily dose of Brufen should not exceed 500 mg. Elderly: The elderly are at increased risk of serious consequences of adverse reactions. If an NSAID is considered necessary, the lowest effective dose should be used and for the shortest possible duration. The patient should be monitored regularly for GI bleeding during NSAID therapy. If renal or hepatic function is impaired, dosage should be assessed individually. For oral administration. It is recommended that patients with sensitive stomachs take Brufen with food. If taken shortly after eating, the onset of action of Brufen may be delayed. To be taken preferably with or after food. Ensure the bottle is thoroughly shaken before use. A transient sensation of burning in the mouth or throat may occur with Brufen Syrup.

**Contraindications**

Brufen is contraindicated in patients with hypersensitivity to the active substance or to any of the excipients. Brufen should not be used in patients who have previously shown hypersensitivity reactions (e.g. asthma, urticaria, angioedema or rhinitis) after taking ibuprofen, aspirin or other NSAIDs. Brufen is also contraindicated in patients with a history of gastrointestinal bleeding or perforation, related to previous NSAID therapy. Brufen should not be used in patients with active, or history of, ulcer or gastrointestinal haemorrhage (two or more distinct episodes of proven ulceration or bleeding). Brufen should not be given to patients with conditions involving an increased tendency to bleeding. Brufen is contraindicated in patients with severe heart failure (NYHA Class IV), hepatic failure and renal failure. Brufen is contraindicated during the last trimester of pregnancy.

**Special warnings and precautions for use**

Undesirable effects may be minimised by using the lowest effective dose for the shortest duration necessary to control symptoms. Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrose-isomaltase insufficiency should not take this medicine. Brufen Syrup contains sucrose and sorbitol. This should also be taken into account in patients with diabetes mellitus. May be harmful to the teeth. Brufen Syrup contains methyl parahydroxybenzoate and propyl parahydroxybenzoate. May cause allergic reactions (possibly delayed). Brufen syrup also contains sunset yellow (E110). May cause allergic reactions. As with other NSAIDs, ibuprofen may mask the signs of infection. The use of Brufen with concomitant NSAIDs, including cyclooxygenase-2 selective inhibitors, should be avoided due to the increased risk of ulceration or bleeding.

**Elderly**

The elderly have an increased frequency of adverse reactions to NSAIDs, especially gastrointestinal bleeding and perforation, which may be fatal.

**Paediatric population**

There is a risk of renal impairment in dehydrated children and adolescents.

**Gastrointestinal bleeding, ulceration and perforation**

GI bleeding, ulceration or perforation, which can be fatal, has been reported with all NSAIDs at anytime during treatment, with or without warning symptoms or a previous history of serious GI events. The risk of GI bleeding, ulceration or perforation is higher with increasing NSAID doses, in patients with a history of ulcer, particularly if complicated with haemorrhage or perforation, and in the elderly. These patients should commence treatment on the lowest dose available. Combination therapy with protective agents (e.g. misoprostol or proton pump inhibitors) should be considered for these patients, and also for patients requiring concomitant low dose aspirin, or other drugs likely to increase gastrointestinal risk. Patients with a history of gastrointestinal disease, particularly when elderly, should report any unusual abdominal symptoms (especially gastrointestinal bleeding) particularly in the initial stages of treatment. Caution should be advised in patients receiving concomitant medications which could increase the risk of ulceration or bleeding, such as oral corticosteroids, anticoagulants such as warfarin, selective serotonin-reuptake inhibitors or anti-platelet agents such as aspirin. When GI bleeding or ulceration occurs in patients receiving Brufen, the treatment should be withdrawn. NSAIDs should be given with care to patients with a history of ulcerative colitis or Crohn's disease as these conditions may be exacerbated.

**Respiratory disorders and hypersensitivity reactions**

Caution is required if Brufen is administered to patients suffering from, or with a previous history of, bronchial asthma, chronic rhinitis or allergic diseases since NSAIDs have been reported to precipitate bronchospasm, urticaria or angioedema in such patients.

**Cardiac, renal and hepatic impairment**

The administration of an NSAID may cause a dose dependent reduction in prostaglandin formation and precipitate renal failure. The habitual concomitant intake of various similar painkillers further increases this risk. Patients at greatest risk of this reaction are those with impaired renal function, cardiac impairment, liver dysfunction, those taking diuretics and the elderly. For these patients, use the lowest effective dose, for the shortest possible duration and monitor renal function especially in long-term treated patients. Brufen should be given with care to patients with a history of heart failure or hypertension since oedema has been reported in association with ibuprofen administration.

**Cardiovascular and cerebrovascular effects**

Appropriate monitoring and advice are required for patients with a history of hypertension and/or mild to moderate congestive heart failure as fluid retention and oedema have been reported in association with NSAID therapy. Clinical studies suggest that use of ibuprofen, particularly at a high dose (2400 mg/day) may be associated with a small increased risk of arterial thrombotic events such as myocardial infarction or stroke. Overall, epidemiological studies do not suggest that low dose ibuprofen (e.g. ≤ 120 mg/day) is associated with an increased risk of arterial thrombotic events. Patients with uncontrolled hypertension, congestive heart failure (NYHA II-III), established ischaemic heart disease, peripheral arterial disease, and/or cerebrovascular disease should only be treated with ibuprofen after careful consideration and high doses (2400 mg/day) should be avoided. Careful consideration should also be exercised before initiating long-term treatment of patients with risk factors for cardiovascular events (e.g. hypertension, hyperlipidaemia, diabetes mellitus, smoking), particularly if high doses of ibuprofen (2400 mg/day) are required.

**Renal effects**

Caution should be used when initiating treatment with ibuprofen in patients with considerable dehydration. As with other NSAIDs, long-term administration of ibuprofen has resulted in renal papillary necrosis and other renal pathologic changes. Renal toxicity has also been seen in patients in whom renal prostaglandins have a compensatory role in the maintenance of renal perfusion. In these patients, administration of an NSAID may cause a dose-dependent reduction in prostaglandin formation and, secondarily, in renal blood flow, which may cause renal failure. Patients at greatest risk of this reaction are those with impaired renal function, heart failure, liver dysfunction, those taking diuretics and ACE inhibitors and the elderly. Discontinuation of NSAID therapy is usually followed by recovery to the pre-treatment state.

**SLE and mixed connective tissue disease**

In patients with systemic lupus erythematosus (SLE) and mixed connective tissue disorders there may be an increased risk of aseptic meningitis.

**Severe skin reactions**

Serious skin reactions, some of them fatal, including exfoliative dermatitis, Stevens-Johnson syndrome, and toxic epidermal necrolysis, have been reported very rarely in association with the use of NSAIDs. Patients appear to be at highest risk of these reactions early in the course of therapy, the onset of the reaction occurring within the first month of treatment in the majority of cases. Acute generalised exanthematous pustulosis (AGEP) has been reported in relation to ibuprofen-containing products. Brufen should be discontinued at the first appearance of skin rash, mucosal lesions, or any other sign of hypersensitivity.

**Haematological effects**

Ibuprofen, like other NSAIDs, can interfere with platelet aggregation and prolong bleeding time in normal subjects. Brufen should be used with caution in patients with intracranial haemorrhage and bleeding diathesis.

**Aseptic meningitis**

Aseptic meningitis has been observed on rare occasions in patients on ibuprofen therapy. Although it is probably more likely to occur in patients with systemic lupus erythematosus and related connective tissue diseases, it has been reported in patients who do not have an underlying chronic disease.

**Impaired female fertility**

The use of Brufen may impair female fertility and is not recommended in women attempting to conceive. In women who have difficulties conceiving or who are undergoing investigation of infertility, withdrawal of Brufen should be considered.

**Interaction with other medicinal products and other forms of interaction**

Care should be taken in patients treated with any of the following drugs as interactions have been reported in some patients. Antihypertensives, beta-blockers and diuretics: NSAIDs may reduce the effect of antihypertensives, such as ACE inhibitors, angiotensin-II receptor antagonists, beta-blockers and diuretics. Diuretics can also increase the risk of nephrotoxicity of NSAIDs. Cardiac glycosides: NSAIDs may exacerbate cardiac failure, reduce GFR and increase plasma cardiac glycoside levels. Cholestyramine: The concomitant administration of ibuprofen and cholestyramine may reduce the absorption of ibuprofen in the gastrointestinal tract. However, the clinical significance is unknown. Lithium: Decreased elimination of lithium. Methotrexate: NSAIDs may inhibit the tubular secretion of methotrexate and reduce clearance of methotrexate. Ciclosporin: Increased risk of nephrotoxicity. Mifepristone: A decrease in the efficacy of the medicinal product can theoretically occur due to the antiprostaglandin properties of NSAIDs. Limited evidence suggests that coadministration of NSAIDs on the day of prostaglandin administration does not adversely influence the effects of mifepristone or the prostaglandin on cervical ripening or uterine contractility and does not reduce the clinical efficacy of medicinal termination of pregnancy. Other analgesics and cyclooxygenase-2 selective inhibitors: Avoid concomitant use of two or more NSAIDs, including Cox-2 inhibitors, as this may increase the risk of adverse effects. Aspirin (Acetylsalicylic acid): As with other products containing NSAIDs, concomitant administration of ibuprofen and aspirin is not generally recommended because of the potential of increased adverse effects. Experimental data suggest that ibuprofen may competitively inhibit the effect of low dose aspirin on platelet aggregation when they are dosed concomitantly. Although there are uncertainties regarding extrapolation of these data to the clinical situation, the possibility that regular, long-term use of ibuprofen may reduce the cardioprotective effect of low-dose acetylsalicylic acid cannot be excluded. No clinically relevant effect is considered to be likely for occasional use. Corticosteroids: Increased risk of gastrointestinal ulceration or bleeding with NSAIDs. Anticoagulants: NSAIDs may enhance the effects of anticoagulants, such as warfarin. Quinolone antibiotics: Animal data indicate that NSAIDs can increase the risk of convulsions associated with quinolone antibiotics. Patients taking NSAIDs and quinolones may have an increased risk of developing convulsions. Sulfonylureas: NSAIDs may potentiate the effects of sulfonylurea medications. There have been rare reports of hypoglycaemia in patients on sulfonylurea medications receiving ibuprofen. Anti-platelet agents and selective serotonin reuptake inhibitors (SSRIs): Increased risk of gastrointestinal bleeding with NSAIDs. Tacrolimus: Possible increased risk of nephrotoxicity when NSAIDs are given with tacrolimus. Zidovudine: Increased risk of haematological toxicity when NSAIDs are given with zidovudine. There is evidence of an increased risk of haemarthroses and haematoma in HIV(+) haemophiliacs receiving concurrent treatment with zidovudine and ibuprofen. Aminoglycosides: NSAIDs may decrease the excretion of aminoglycosides. Herbal extracts: Ginkgo biloba may potentiate the risk of bleeding with NSAIDs. CYP2C9 inhibitors: Concomitant administration of ibuprofen with CYP2C9 inhibitors may increase the exposure to ibuprofen (CYP2C9 substrate). In a study with vortioxazine and fluconazole (CYP2C9 inhibitors), an increased S(+)-ibuprofen exposure by approximately 80 to 100% has been shown. Reduction of the ibuprofen dose should be considered when potent CYP2C9 inhibitors are administered concomitantly, particularly when high-dose ibuprofen is administered with either voriconazole or fluconazole.

**Pregnancy and lactation**

**Pregnancy**  
Inhibition of prostaglandin synthesis may adversely affect the pregnancy and/or embryo/foetal development. Data from epidemiological studies suggest an increased risk of miscarriage and of cardiac malformation and gastroschisis after the use of a prostaglandin synthesis inhibitor in early pregnancy. The risk is believed to increase with dose and duration of therapy. In animals, the administration of a prostaglandin synthesis inhibitor has been shown to result in increased pre- and post-implantation losses and embryo/foetal lethality. In addition, increased incidences of various malformations, including cardiovascular, have been reported in animals given a prostaglandin synthesis inhibitor during the organogenetic period. During the first and second trimester of pregnancy, Brufen should not be given unless clearly necessary. If Brufen is used by a woman attempting to conceive, or during the first or second trimester of pregnancy, the dose should be kept as low and duration of treatment as short as possible. During the second trimester, NSAIDs should not be used starting from around 20 to 28 weeks of pregnancy, unless advised by the healthcare professional.

The use of non-steroid anti-inflammatory drugs (NSAIDs), starting from approximately 20 weeks of pregnancy or later, may cause rare but serious kidney problems in an

unborn baby. This can lead to low levels of amniotic fluid and possible complications

The use of NSAIDs must not be used in the last trimester of pregnancy (i.e., beyond 28 weeks to the end of pregnancy).

During the third trimester of pregnancy, all prostaglandin synthesis inhibitors may expose the foetus to the following:

- Cardiopulmonary toxicity (with premature closure of the ductus arteriosus and pulmonary hypertension)
  - Renal dysfunction, which may progress to renal failure with oligohydramnios.
- At the end of pregnancy, prostaglandin synthesis inhibitors may expose the mother and the neonate to the following:
- Possible prolongation of bleeding time
  - Inhibition of uterine contractions, which may result in delayed or prolonged labour. Consequently, Brufen is contraindicated during the third trimester of pregnancy

Consult your healthcare professional if you are pregnant and have used NSAIDs and have health concerns.

**Labour and delivery:**

Administration of ibuprofen is not recommended during labour and delivery. The onset of labour may be delayed and the duration increased with a greater bleeding tendency in both mother and child.

**Lactation**

In the limited studies so far available, NSAIDs can appear in the breast milk in very low concentrations. NSAIDs should, if possible, be avoided when breastfeeding. See "Special warnings and precautions for use, regarding female fertility".

**Effects on ability to drive and use machines**

Undesirable effects such as dizziness, drowsiness, fatigue and visual disturbances are possible after taking NSAIDs. If affected, patients should not drive or operate machinery.

**Undesirable effects**

Gastrointestinal disorders: The most commonly observed adverse events are gastrointestinal in nature. Peptic ulcers, perforation or GI bleeding, sometimes fatal, particularly in the elderly, may occur. Nausea, vomiting, diarrhoea, flatulence, constipation, dyspepsia, abdominal pain, melena, haematemesis, ulcerative stomatitis, gastrointestinal haemorrhage and exacerbation of colitis and Crohn's disease have been reported following ibuprofen administration. Less frequently, gastritis, duodenal ulcer, gastric ulcer and gastrointestinal perforation have been observed. A transient sensation of burning in the mouth or throat may occur with Brufen Syrup.

Immune system disorders: Hypersensitivity reactions have been reported following treatment with NSAIDs. These may consist of (a) non-specific allergic reaction and anaphylaxis, (b) respiratory tract reactivity comprising asthma, aggravated asthma, bronchospasm or dyspnoea, or (c) assorted skin disorders, including rashes of various types, pruritus, urticaria, purpura, angioedema and, very rarely, erythema multiforme, bullous dermatoses (including Stevens-Johnson syndrome and toxic epidermal necrolysis). Cardiac disorders and vascular disorders: Oedema, hypertension and cardiac failure have been reported in association with NSAID treatment. Clinical studies suggest that use of ibuprofen, particularly at high dose (2400 mg/day) may be associated with a small increased risk of arterial thrombotic events such as myocardial infarction or stroke. Infections and infestations: Rhinitis and aseptic meningitis (especially in patients with existing autoimmune disorders, such as systemic lupus erythematosus and mixed connective tissue disease) with symptoms of stiff neck, headache, nausea, vomiting, fever or disorientation. Exacerbation of infection-related inflammations coinciding with the use of NSAIDs has been described. If signs of an infection occur or get worse during use of ibuprofen the patient is therefore recommended to go to a doctor without delay. Skin and subcutaneous tissue disorders: In exceptional cases, severe skin infections and soft-tissue complications may occur during a varicella infection (see also "Infections and infestations").

The following adverse reactions possibly related to ibuprofen and displayed by MedDRA frequency convention and system organ classification. Frequency groupings are classified according to the subsequent conventions: very common (≥1/10), Common (≥1/100 to <1/10), Uncommon (≥1/1,000 to <1/100), Rare (≥1/10,000 to <1/1,000), Very rare (<1/10,000) and Not known (cannot be estimated from the available data).

System organ class	Frequency	Adverse reaction
Infections and infestations	Uncommon	Rhinitis
	Rare	Meningitis aseptic
Blood and lymphatic system disorders	Rare	Leukopenia, thrombocytopenia, neutropenia, agranulocytosis, aplastic anaemia, haemolytic anaemia
	Uncommon	Hypersensitivity
Immune system disorders	Rare	Anaphylactic reaction
	Uncommon	Insomnia, anxiety
Psychiatric disorders	Rare	Depression, confusional state
	Common	Headache, dizziness
Nervous system disorders	Uncommon	Paraesthesia, somnolence
	Rare	Optic neuritis
Eye disorders	Uncommon	Visual impairment
	Rare	Toxic optic neuropathy
Ear and labyrinth disorders	Uncommon	Hearing impaired, tinnitus, vertigo
	Uncommon	Asthma, bronchospasm, dyspnoea
Gastrointestinal disorders	Common	Dyspepsia, diarrhoea, nausea, vomiting, abdominal pain, flatulence, constipation, melena, haematemesis, gastrointestinal haemorrhage
	Uncommon	Gastritis, duodenal ulcer, gastric ulcer, mouth ulceration, gastrointestinal perforation
	Very rare	Pancreatitis
	Not known	Exacerbation of Colitis and Crohn's disease
Hepatobiliary disorders	Uncommon	Hepatitis, jaundice, hepatic function abnormal
	Very Rare	Hepatic failure
Skin and subcutaneous tissue disorders	Common	Rash
	Uncommon	Urticaria, pruritus, purpura, angioedema, photosensitivity reaction
	Very rare	Severe forms of skin reactions (e.g. Erythema multiforme, bullous reactions, including Stevens-Johnson syndrome, and toxic epidermal necrolysis)
Renal and urinary disorders	Uncommon	Drug reaction with eosinophilia and systemic symptoms (DRESS syndrome) Acute generalised exanthematous pustulosis (AGEP)
	Uncommon	Nephrotoxicity in various forms e.g. tubulointerstitial nephritis, nephrotic syndrome and renal failure
General disorders and administration site conditions	Common	Fatigue
	Rare	Oedema
Cardiac disorders	Very rare	Cardiac failure, myocardial infarction
Vascular disorders	Very rare	Hypertension

**Reporting of suspected adverse reactions**

If you get any side effects, talk to your doctor or pharmacist. By reporting side effects you can help provide more information on the safety of this medicine.

**Overdose**

**Toxicity**

Signs and symptoms of toxicity have generally not been observed at doses below 100 mg/kg in children. However, supportive care may be needed in some cases. Children have been observed to manifest signs and symptoms of toxicity after ingestion of 400 mg/kg or greater.

**Symptoms**

Most patients who have ingested significant amounts of ibuprofen will manifest symptoms within 4 to 6 hours. The most frequently reported symptoms of overdose include nausea, vomiting, abdominal pain, lethargy and drowsiness. Central nervous system (CNS) effects include headache, tremor, dizziness, convulsion, and loss of consciousness. Nystagmus, metabolic acidosis, hypothermia, renal effects, gastrointestinal bleeding, coma, apnoea, diarrhoea and depression of the CNS and respiratory system have also been rarely reported. In serious poisoning metabolic acidosis may occur. Disorientation, excitation, fainting and cardiovascular toxicity, including hypotension, bradycardia and tachycardia have been reported. In cases of significant overdose, renal failure and liver damage are possible. Large overdoses are generally well tolerated when no other drugs are being taken.

**Therapeutic measures**

Patients should be treated symptomatically as required. Within one hour of ingestion of a potentially toxic amount, activated charcoal should be considered. Alternatively, in adults, gastric lavage should be considered within one hour of ingestion of a potentially life-threatening overdose. Good urine output should be ensured. Renal and liver function should be closely monitored. Patients should be observed for at least four hours after ingestion of potentially toxic amounts. Frequent or prolonged convulsions should be treated with intravenous diazepam. Other measures may be indicated by the patient's clinical condition.

**Pharmacological properties**

**Pharmacodynamic properties**

Pharmacotherapeutic classification: Anti-inflammatory and antirheumatic products, nonsteroidal; propionic acid derivatives. ATC code: M01AE01 Ibuprofen is a propionic acid derivative with analgesic, anti-inflammatory and anti-pyretic activity. The drug's therapeutic effects as an NSAID is thought to result from its inhibitory effect on the enzyme cyclo-oxygenase, which results in a marked reduction in prostaglandin synthesis. Experimental data suggest that ibuprofen may competitively inhibit the effect of low dose aspirin on platelet aggregation when they are dosed concomitantly. Some pharmacodynamic studies show that when single doses of ibuprofen 400 mg were taken within 8 hours before or within 30 minutes after immediate release aspirin dosing (81 mg), a decreased effect of aspirin on the formation of thromboxane or platelet aggregation occurred. Although there are uncertainties regarding extrapolation of these data to the clinical situation, the possibility that regular, long-term use of ibuprofen may reduce the cardioprotective effect of low-dose acetylsalicylic acid cannot be excluded. No clinically relevant effect is considered to be likely for occasional ibuprofen use.

**Pharmacokinetic properties**

Ibuprofen is rapidly absorbed from the gastrointestinal tract, peak serum concentrations occurring 1-2 hours after administration. The elimination half-life is approximately 2 hours. Ibuprofen is metabolised in the liver to two inactive metabolites and these, together with unchanged ibuprofen, are excreted by the kidney either as such or as conjugates. Excretion by the kidney is both rapid and complete. Ibuprofen is extensively bound to plasma proteins.

**Preclinical safety data**

Not applicable.

**Pharmaceutical particulars**

**List of excipients**

Methyl hydroxybenzoate  
Propyl hydroxybenzoate  
Refined sugar  
Citric acid monohydrate granular  
Sodium benzoate  
Agar powder  
Glycerin  
Saturated solution 70% (non-crystallising)  
Polysorbate 80  
Sunset yellow  
Orange flavour D717  
Purified water

**Incompatibilities**

None known.

**Shelf life**

36 months. Once the bottle is opened, the Brufen Syrup should be used within 12 months.

**Special precautions for storage**

Store below 25°C and protect from light.

**Nature and contents of container**

An amber-coloured polyethylene terephthalate (PET) bottle with an aluminium cap fitted with a low-density polyethylene liner. Pack sizes of 100ml & 200ml

**Special precautions for disposal and other handling**

None stated.

**Bulk Manufactured by:**

AbbVie S.r.l., S.R. 148 Pontina Km 52 snc - 04011 Campoverde di Aprilia (LT), Italy

**Released by:**

Neopharma, Plot A-1 89-95, Industrial City of Abu Dhabi (ICAD), Musaffah, P.O.Box 72900, Abu Dhabi, UAE.

**For:**

Abbott Laboratories GmbH  
Dubai Healthcare City, Dubai, P.O. Box 505121, UAE

**Date of revision of the text**

30-11-2021

**THIS MEDICATION**  
is a product which affects your health and its use contrary to instructions is dangerous to you. Strictly follow the doctor's prescription, the method of use and the instructions of the pharmacist who sold you the medication.  
- The doctor and the pharmacist are the experts in medicines, their benefits and risks.  
- Do not interrupt the period of treatment prescribed without talking to your doctor first.  
- Do not repeat the same prescription without first consulting your doctor.  
- Keep all medications out of reach of children.  
Council of Arab Health Ministers.  
Union of Arab Pharmacists.

**Abbott**  
AW-946-R2

