



Noroprofen 200mg Tablets

PL 02000/0057

UKPAR

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Noroprofen 200mg Tablets

PL 02000/0057

LAY SUMMARY

The MHRA granted Norbrook Laboratories Limited Marketing Authorisation (licence) for the medicinal product Noroprofen 200mg Tablets (PL 02000/0057) on 17th July 2007. This general sale list medicine (GSL) is indicated for the treatment of headache, migraine, dental pain, backache, rheumatic or muscular pain, neuralgia, period pain, feverishness and symptoms of cold and flu.

This application is a duplicate of a previously granted application for Ibuprofen tablets 200mg (PL 22959/0002).

No new or unexpected safety concerns arose from this simple application and it was, therefore, judged that the benefits of taking Noroprofen 200mg Tablets outweigh the risks, hence Marketing Authorisation has been granted.

Noroprofen 200mg Tablets

PL 02000/0057

SCIENTIFIC DISCUSSION

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INTRODUCTION

The UK granted a marketing authorisation for the medicinal product Noroprofen 200mg Tablets (PL 02000/0057) to Norbrook Laboratories Limited on 17th July 2007. The product is a general sale list (GSL).

The application was submitted as a “simple” abridged application according to article 10(c) of Directive 2001/83/EC, cross-referring to Ibuprofen tablets 200mg (PL 22959/0002) approved to Line Range Limited.

No new data was submitted nor was it necessary for this simple application, as the data is identical to that of the previously granted cross-reference product. As the cross-reference product was granted prior to the introduction of current legislation, no PARs was generated.

Noroprofen tablets contain the active ibuprofen, which is one of a group of medicines called non-steroidal anti-inflammatory drugs or NSAIDS. It relieves pain, reduces inflammation and lowers temperature when you are feverish.

PHARMACEUTICAL ASSESSMENT

LICENCE NO: PL 02000/0057

PROPRIETARY NAME: Noroprofen 200mg Tablets & Ibuprofen 200mg Tablets
BP

ACTIVE(S): Ibuprofen

COMPANY NAME: Norbrook Laboratories Limited

E.C. ARTICLE: Article 10 (c) of Directive 2001/83/EC

LEGAL STATUS: GSL

1. INTRODUCTION

This is a simple abridged application for Noroprofen 200mg Tablets & Ibuprofen 200mg Tablets BP submitted under Article 10 (c) of Directive 2001/83/EC. The proposed MA holder is “Norbrook Laboratories Limited, Station Works, Camlough Road, Newry, CO Down, BT35 6JP, United Kingdom”

This application refers to a Marketing Authorisation granted to Line Range Limited (Ibuprofen 200 mg tablets, PL 22959/0002). It has been indicated in the application form that two invented names, Noroprofen 200mg and Ibuprofen 200mg BP are being applied for, the names are acceptable.

A letter of access has been provided from Line Range Ltd dated 07 January 2006 authorising the MHRA to refer to PL 22959/0002 as the reference for the purpose of this informed consent application. A signed declaration by Norbrook Laboratories Ltd stating that they have the relevant Quality dossier for PL 22959/0002 in their possession has been provided.

Preclinical, pharmaceutical and clinical expert statements have been provided together with CVs showing the experts are appropriately qualified. The experts confirm that the products are identical in composition, manufacture and pharmaceutical characteristics to the respective reference product and that there are no toxicological or clinical issues.

2. MARKETING AUTHORISATION APPLICATION FORM

2.1 Name(s)

The proposed names of the product is Noroprofen 200mg Tablets /Ibuprofen 200mg tablets. The product has been named in line with current requirements.

2.2 Strength, pharmaceutical form, route of administration, container and pack sizes

The product contains the active ingredient ibuprofen BP 200mg. It will be packaged into PVC/aluminium blisters only. The packagings are identical to the blister packaging used for the reference product.

The respective SPC have indicated that Noroprofen 200mg or Ibuprofen 200mg will be packed into blister packs with a pack size of 12 and 16 only as restricted for GSL sale. The same pack sizes are stated in the reference product. The proposed shelf life of 60 months (5 years) is identical to the reference product. The proposed storage conditions for the container closure system is also consistent with the details registered for the cross-reference product.

2.3 Legal status

The product is General Sale List (GSL).

2.4 Marketing authorisation holder/Contact Persons/Company

The proposed Marketing Authorisation holder is Norbrook Laboratories Limited, Station Works, Camlough Road, Newry, CO Down, BT35 6JP, United Kingdom.

The QP responsible for pharmacovigilance is stated and a CV is included.

2.5 Manufacturers

The proposed manufacturing sites are consistent with that registered for the cross-reference product and evidence of GMP compliance has been provided. A flow diagram showing the sequence and activities of the different sites involved in the manufacturing process has been provided.

2.6 Qualitative and quantitative composition

The proposed compositions are consistent with the details registered for the cross-reference products.

2.7 Manufacturing process

The proposed manufacturing process is consistent with the details registered for the cross-reference products and the maximum batch size is stated.

2.8 Finished product/shelf-life specification

The proposed finished product specification is in line with the details registered for the cross-reference products.

2.9 Drug substance specification

The proposed drug substance specification conformed to current Ph Eur monograph for ibuprofen and was consistent with that of the reference product.

Current Ph Eur certificates of suitability for all three drug substance manufacturer have been provided to support the sources of active substance. These manufacturers are in line with the reference product.

2.10 TSE Compliance

TSE declaration has been provided for the excipients lactose and magnesium stearate.

3. EXPERT REPORTS

The applicant has included detailed expert reports of the application. Signed declarations and copies of the experts' CVs are enclosed for the quality, non-clinical and clinical experts. All are considered to have sufficient experience for their responsibilities.

4. PRODUCT NAME & APPEARANCE

See 2.1 for details of the proposed product names. The appearances of the products are identical to the cross-reference products.

5. SUMMARY OF PRODUCT CHARACTERISTICS

The proposed SmPCs are consistent with the details registered for the cross-reference product.

6. PATIENT INFORMATION LEAFLET/BLISTER

PIL

The patient information leaflet has been prepared in-line with the details registered for the cross-reference products.

The result of user testing has been provided

The proposed artwork complies with the relevant statutory requirements. In line with current legislation the applicant has also included the name of the product in Braille on the outer packaging and has included sufficient space for a standard UK pharmacy dispensing label.

7. CONCLUSIONS

The data submitted with the application is acceptable. Marketing Authorisation should be granted.

PRECLINICAL ASSESSMENT

No new preclinical data have been supplied with this application and none are required for an application of this type.

CLINICAL ASSESSMENT

As this is a duplicate application of PL 22959/0002, no new clinical data have been supplied and none are required.

OVERALL CONCLUSION AND RISK BENEFIT ASSESSMENT

QUALITY

The data for this application are consistent with that previously assessed for the cross-reference product and as such has been judged to be satisfactory.

PRECLINICAL

No new preclinical data were submitted and none are required for an application of this type.

EFFICACY

Ibuprofen is a well known drug and has been used for many years. This application is identical to a previously granted application for Ibuprofen 200 mg tablets (PL 22959/0002).

Preclinical, pharmaceutical and clinical expert statements have been provided together with CVs showing the experts are appropriately qualified. The experts confirm that the product is identical in composition, manufacture and pharmaceutical characteristics to the respective reference product and that there are no toxicological or clinical issues.

No new or unexpected safety concerns arise from this application.

The SPC, PIL and labelling are satisfactory and consistent with that for the cross-reference product.

RISK BENEFIT ASSESSMENT

The quality of the product is acceptable and no new preclinical or clinical safety concerns have been identified. The applicant's product is identical to the cross-reference product. Extensive clinical experience with ibuprofen is considered to have demonstrated the therapeutic value of the compound. The risk benefit is therefore considered to be positive.

STEPS TAKEN FOR ASSESMENT

1	The MHRA received the marketing authorisation application on 18/04/2006.
2	Following standard checks and communication with the applicant the MHRA considered the application valid on 16/05/2006.
3	Following assessment of the application the MHRA requested further information on 17/07/2006 and 13/11/2006.
4	The applicant responded to the MHRA's requests, providing further information on 06/11/2006 and 21/03/2007.
7	The application was determined on 17/07/2007

Noroprofen 200mg Tablets

PL 02000/0057

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Ibuprofen 200mg Tablets BP

Noroprofen 200mg Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains Ibuprofen BP 200mg.

Also contains lactose, sucrose and sunset yellow.

For excipients see section 6.1

3 PHARMACEUTICAL FORM

Pink sugar coated tablets

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Rheumatic or muscular pain, backache, neuralgia, migraine, headache, dental pain, dysmenorrhoea, feverishness, symptoms of colds and influenza.

4.2 Posology and method of administration

Adults, the elderly and children over 12 years: 1 or 2 tablets to be taken every four hours if necessary, up to three times a day, with or after food. Tablets should be swallowed with water. The dosage should not be repeated more frequently than every four hours and no more than 6 tablets should be taken in any 24 hour period.

4.3 Contraindications

Hypersensitivity to any of the constituents.

Hypersensitivity reactions to Aspirin or other non-steroidal anti-inflammatory drugs, including asthma, rhinitis or urticaria.

Current or previous peptic ulceration.

Stomach bleeding.

Severe heart failure.

Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactase malabsorption should not take this medicine.

Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine.

4.4 Special warnings and precautions for use

Bronchospasm may be precipitated in patients suffering from or with a previous history of bronchial asthma or allergic disease.

Ibuprofen should only be given with care to patients with a history of gastrointestinal disease.

Caution (discussion with doctor or pharmacist) is required prior to starting treatment in patients with a history of hypertension and/or heart failure as fluid retention, hypertension and oedema have been reported in association with NSAID therapy.

Undesirable effects may be minimised by using the lowest effective dose for the shortest duration necessary to control symptoms (see GI and cardiovascular risks below).

The elderly are at increased risk of the serious consequences of adverse reactions.

Caution is required in patients with renal, cardiac or hepatic impairment since renal function may deteriorate. The dose should be as low as possible and renal function monitored.

Cardiovascular and cerebrovascular effects

Clinical trial and epidemiological data suggest that use of ibuprofen, particularly at high doses (2400mg daily) and in long-term treatment may be associated with a small increased risk of arterial thrombotic events (for example myocardial infarction or stroke). Overall, epidemiological studies do not suggest that low dose ibuprofen (e.g. ≤ 1200 mg daily) is associated with an increased risk of myocardial infarction.

4.5 Interaction with other medicinal products and other forms of interaction

Concurrent aspirin or other NSAIDs may result in an increased incidence of adverse reactions. May enhance the effects of anti-coagulants and Lithium. NSAIDs may diminish the effect of anti-hypertensives or thiazide diuretics.

NSAIDs may exacerbate cardiac failure, reduce GFR and increase plasma cardiac glycoside levels.

There is an increased risk of gastrointestinal bleeding with corticosteroids and an increased risk of nephrotoxicity with cyclosporin.

NSAIDs should not be used for 8-12 days after mifepristone administration as NSAIDs can reduce the effect of mifepristone.

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.

4.6 Pregnancy and lactation

Whilst no teratogenic effects have been demonstrated in animal studies, ibuprofen should be avoided during pregnancy.

The onset of labour may be delayed and duration of labour increased.

Ibuprofen appears in breast milk in very low concentration and is unlikely to affect the breast-fed infant adversely.

4.7 Effects on ability to drive and use machines

No or negligible effects.

4.8 Undesirable effects

Gastrointestinal: The most commonly observed adverse events are gastrointestinal in nature. Abdominal pain, nausea, vomiting, diarrhoea, melaena, haematemesis, ulcerative stomatitis and dyspepsia. Occasionally, gastritis, duodenal ulcer, intestinal perforation, peptic ulcer and gastrointestinal haemorrhage have been observed. Epidemiological data indicate that of the seven most widely-used oral non-aspirin NSAIDs, ibuprofen presents the lowest risk of gastrointestinal toxicity.

Cardiovascular: Oedema, hypertension, and cardiac failure have been reported in association with NSAID treatment.

Clinical trial and epidemiological data suggest that use of ibuprofen (particularly at high doses 2400mg daily) and in long-term treatment may be associated with a small increased risk of arterial thrombotic events (for example myocardial infarction or stroke) (see section 4.4).

Renal: papillary necrosis which can lead to renal failure.

Other adverse events reported less commonly and for which causality has not necessarily been established include:

Haematological: thrombocytopenia, neutropenia, agranulocytosis, aplastic anaemia and haemolytic anaemia.

Others: rarely hepatic dysfunction, headache, dizziness, hearing disturbance, photosensitivity, visual disturbances, optic neuritis, paraesthesia, depression, confusion, hallucinations, vertigo, malaise, fatigue and drowsiness

Hypersensitivity reactions have been reported following treatment with ibuprofen. These may consist of (a) non-specific allergic reaction and anaphylaxis, (b) respiratory tract reactivity comprising of asthma, aggravated asthma, bronchospasm or dyspnoea, or (c) assorted skin disorders, including rashes of various types, pruritis,

urticaria, purpura, angiodema and, less commonly, bullous dermatoses (including epidermal necrolysis and erythema multiforme).

4.9 Overdose

Symptoms of overdose include headache, nausea, vomiting, epigastric pain, vertigo, sleepiness, hypotension, ataxia and very occasionally coma.

No specific antidote is available. Treatment is supportive with gastric lavage and correction of serum electrolyte imbalance if required.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

ATC Code: M01A E01

Pharmacotherapeutic group: Anti-inflammatory and anti-rheumatic product, non steroid, propionic acid derivative

Ibuprofen has analgesic, antipyretic and anti-inflammatory properties

Ibuprofen inhibits prostaglandin synthesis.

5.2 Pharmacokinetic properties

Ibuprofen is rapidly absorbed following administration and is rapidly distributed throughout the whole body. The excretion is rapid and complete via the kidneys.

Maximum plasma concentrations are reached 45 minutes after ingestion if taken on an empty stomach. When taken with food peak levels are observed after 1 to 2 hours.

The half life of Ibuprofen is about 2 hours.

In limited studies Ibuprofen appears in the breast milk in very low concentrations.

5.3 Preclinical safety data

There is no pre-clinical data of relevance to a prescriber which is additional to that already included in other sections of the SmPC.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Tablet core:

Lactose, starch, methyl cellulose, sodium starch glycollate, colloidal anhydrous silica, magnesium stearate,

Tablet coating:

Sucrose, talc, titanium dioxide (E171), Mastercote SP0478 (*sucrose, titanium dioxide (E171), sunset yellow (E110), erythrosine (E127), sodium benzoate (E211), purified water*).

6.2 Incompatibilities

None stated.

6.3 Shelf life

5 years.

6.4 Special precautions for storage

Store below 25°C. Store in the original package.

6.5 Nature and contents of container

Ibuprofen Tablets are available in blister packs of 12 and 16 tablets.

Noroprofen Tablets are available in blister packs of 12 and 16 tablets.

Specification details of blister packs:

- PVC (white, rigid, opaque): 250 microns
- Aluminium foil (hard tempered): 20 microns
- Primer (nitrocellulose): 1.5 -2.5 gsm
- Heat seal lacquer: 6.5 - 8.5 gsm

6.6 Special precautions for disposal

No special requirements

7 MARKETING AUTHORISATION HOLDER

Norbrook Laboratories Limited
Station Works
Camlough Road
Newry Co. Down
BT35 6JP
United Kingdom

8 MARKETING AUTHORISATION NUMBER(S)

PL 02000/0057

**9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE
AUTHORISATION**

17/07/2007

10 DATE OF REVISION OF THE TEXT

17/07/2007

To listen to or request a copy of this leaflet in Braille, large print or audio please call, free of charge: 0800 198 5000 (UK Only). Please be ready to give the following information:

Product name: Noroprofen 200mg Tablets BP

Reference number: 02000/0057

This is a service provided by the Royal National Institute of the Blind.

Patient Information Leaflet

GSL

Noroprofen 200mg Tablets

Ibuprofen

Please read this leaflet carefully before you start to take Noroprofen Tablets. If you have any questions or if you do not understand anything, please ask your doctor or pharmacist.

What does the active ingredient do?

Ibuprofen is one of a group of medicines called non-steroidal anti-inflammatory drugs or NSAIDs. It relieves pain, reduces inflammation and lowers temperature when you are feverish.

What is it used for?

Noroprofen Tablets are used to provide relief of headache, migraine, dental pain, backache, rheumatic and muscular pains, neuralgia, period pain, feverishness and the symptoms of cold and flu.

Do not take this medicine if:

- You are allergic to ibuprofen, aspirin or any other painkillers or to any of the other ingredients contained in the tablets. An allergic reaction may be recognised as a rash, itching, swollen face or lips, or shortness of breath.
- You are or have been suffering from a stomach or duodenal ulcer or other stomach disorders.
- You are taking aspirin or any other non-steroidal anti-inflammatory drugs (NSAIDs).

See your doctor before you take this medicine if:

- You suffer from asthma or hives.
- You have been prescribed drugs to thin the blood (anticoagulants), for high blood pressure or heart disease, lithium (used in the treatment of mania) or diuretics (water tablets).
- You are taking corticosteroids (used to treat hormone problems, inflammation or allergic conditions), cyclosporin (used following organ transplants), mifepristone (used to induce abortion), or antibiotics called quinolones (such as ciprofloxacin).
- You have liver, kidney or heart problems.
- You are pregnant or breast-feeding.
- You have a history of heart problems or high blood pressure.
- If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

If you are elderly you may be more prone to side effects so you should take just enough to make you feel better. The colouring includes sunset yellow (E110), which can cause allergic-type reactions including asthma. Allergy is more common in those people who are allergic to aspirin.

Medicines such as Ibuprofen Tablets may be associated with a small increased risk of heart attack ("myocardial infarction") or stroke. Any risk is more likely with high doses and prolonged treatment. Do not exceed the recommended dose or duration of treatment (3 days).

If you have heart problems, previous stroke or think you might be at risk of these conditions (for example if you have high blood pressure, diabetes or high cholesterol or are a smoker) you should discuss your treatment with your doctor or pharmacist.

How to take Noroprofen Tablets:

They are suitable for adults, the elderly and children over 12 years old:

Dose for Noroprofen Tablets 200mg:

- Take one to two tablets with water to start with, preferably with or after food, followed by one to two tablets every four hours if necessary up to three times a day.
- Do not take more than six tablets in any twenty four hour period.

Do not continue to use for longer than three days without consulting your pharmacist or doctor.

The side effects may be minimised by using the lowest effective dose for the shortest possible time.

DO NOT GIVE TO CHILDREN UNDER 12 YEARS OLD**CONSULT YOUR DOCTOR IMMEDIATELY IF YOU HAVE TAKEN TOO MANY TABLETS**

If you have missed a dose, do not double up on a dose to make up for the one you have missed.

Possible side effects

In most cases, taking Noroprofen Tablets does not cause any problems. If you experience any of the following, stop taking the medicine immediately and tell your doctor: unexplained wheezing, shortness of breath, skin rash, itching, bruising or facial swelling.

Other side effects that could occur include:

- Sick feeling, nausea, digestive problems such as stomach pain, heartburn and peptic ulcer and occasionally stomach bleeding may occur (signs of this can be black tarry stools or vomiting).
- Allergic reactions such as skin rashes, itching, runny nose difficulty breathing and, very rarely, skin peeling.
- Rarely changes in the blood which may lead to bruising.
- Blood in urine, kidney damage or kidney failure has been reported.
- Swelling of the heart.
- Rarely liver problems. Also headache, dizziness, vertigo, ringing in the ears, sensitivity to light, visual disturbances, 'pins and needles', depression, confusion, hallucinations, tiredness, drowsiness and vertigo.
- A worsening of a previous asthmatic condition.
- Medicines such as Ibuprofen Tablets may be associated with a small increased risk of heart attack ("myocardial infarction") or stroke.

If you experience these or any other unusual side effects, stop taking this medicine and tell your doctor or pharmacist at once.

TELL YOUR PHARMACIST OR YOUR DOCTOR IF YOU ARE ALREADY TAKING OTHER MEDICINES**Further information:**

- Store below 25°C. Store in the original package.
- Do not use after the expiry date shown on the package.

What does each tablet contain?

Each tablet contains the active ingredient Ibuprofen BP 200mg. The tablets also contain: lactose, sucrose, starch, methyl cellulose, sodium starch glycollate, colloidal anhydrous silica, magnesium stearate, talc, titanium dioxide (E171), erythrosine (E127), sunset yellow (E110) and sodium benzoate (E211).

What is in the pack?

This product contains pink round sugar coated tablets. Noroprofen Tablets 200mg are available in blister packs of 12 and 16 tablets.

Who supplies Noroprofen Tablets?

The Product Licence holder and the manufacturer is:
Norbrook Laboratories Limited, Station Works, Newry, Co. Down, BT35 6JP, Northern Ireland.

KEEP OUT OF THE REACH OF CHILDREN

Leaflet prepared: February 2007

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Norbrook

To listen to or request a copy of this leaflet in Braille, large print or audio please call, free of charge: 0800 198 5000 (UK Only). Please be ready to give the following information:

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Reference number: 02000/0057

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Patient Information Leaflet

GSL

Ibuprofen 200mg Tablets BP

Please read this leaflet carefully before you start to take Ibuprofen Tablets. If you have any questions or if you do not understand anything, please ask your doctor or pharmacist.

What does the active ingredient do?

Ibuprofen is one of a group of medicines called non-steroidal anti-inflammatory drugs or NSAIDs. It relieves pain, reduces inflammation and lowers temperature when you are feverish.

What is it used for?

Ibuprofen Tablets are used to provide relief of headache, migraine, dental pain, backache, rheumatic and muscular pains, neuralgia, period pain, feverishness and the symptoms of cold and flu.

Do not take this medicine if:

- You are allergic to ibuprofen, aspirin or any other painkillers or to any of the other ingredients contained in the tablets. An allergic reaction may be recognised as a rash, itching, swollen face or lips, or shortness of breath.
- You are or have been suffering from a stomach or duodenal ulcer or other stomach disorders.
- You are taking aspirin or any other non-steroidal anti-inflammatory drugs (NSAIDs).

See your doctor before you take this medicine if:

- You suffer from asthma or hives.
- You have been prescribed drugs to thin the blood (anticoagulants), for high blood pressure or heart disease, lithium (used in the treatment of mania) or diuretics (water tablets).
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Medicines such as Ibuprofen Tablets may be associated with a small increased risk of heart attack ("myocardial infarction") or stroke. Any risk is more likely with high doses and prolonged treatment. Do not exceed the recommended dose or duration of treatment [3 days].

If you have heart problems, previous stroke or think you might be at risk of these conditions (for example if you have high blood pressure, diabetes or high cholesterol or are a smoker) you should discuss your treatment with your doctor or pharmacist.

How to take Ibuprofen Tablets:

They are suitable for adults, the elderly and children over 12 years old:

Dose for Ibuprofen Tablets BP 200mg:

- Take one to two tablets with water to start with, preferably with or after food, followed by one to two tablets every four hours if necessary up to three times a day.
- Do not take more than six tablets in any twenty four hour period.

Do not continue to use for longer than three days without consulting your pharmacist or doctor.

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Other side effects that could occur include:

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- Rarely changes in the blood which may lead to bruising.
- Blood in urine, kidney damage or kidney failure has been reported.
- Swelling of the heart.
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