

**PATIENT INFORMATION LEAFLET:
IBUFLAM TABLETS/SUSPENSION:
{IBUPROFEN PREPARATIONS}**

Read this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor or pharmacist.
- Do not pass this medicine on to others. It may harm them, even if their symptoms are the same as yours.
- In order that this medicine works, it must be taken exactly as directed.
- Keep all medicines out of reach of children.
- If you want more information about this medicine ask your doctor or pharmacist.

- In this leaflet:
1. What Ibuflam is and what it is used for
 2. Before you use Ibuflam
 3. How to use Ibuflam
 4. Possible side effects
 5. How to store Ibuflam
 6. Further information
 7. Presentation

1. WHAT IS IBUFLAM AND WHAT IS IT USED FOR?

The name of the medicine is Ibuflam. The active ingredients are ibuprofen. Ibuflam is indicated for fever and relief of mild to moderate pain, used as an analgesic for relief of mild to moderate muscular pain, post-immunization pyrexia, symptomatic relief of headache, earache, dental pain and backache. It can also be used in minor injuries such as sprains and strains. It is effective in the relief of feverishness and symptoms of colds and influenza.

Each tablet contains: Ibuprofen 400mg BP
Ibuprofen 200mg BP
Each 5ml contains : Ibuprofen 100mg BP

2. BEFORE YOU USE IBUFLAM:

Do not use Ibuflam without medical advice:
If you have had an allergy to any of the ingredients in the past.
If you are on any other drugs.

3. HOW TO USE IBUFLAM:

Short term symptomatic treatment of fever and pain of mild to moderate intensity:

Adults and adolescents over 12 years (>40 kg)

One or two 200 mg tablets one to four times daily, as needed. An interval of at least 4-6 hours should be allowed between doses. Single doses exceeding 400 mg have not been shown to have any additional analgesic effect.

Dysmenorrhoea

One or two 200mg tablets one to three times daily, as needed. An interval of at least 4-6 hours should be allowed between doses. Treatment is started at the first sign of menstruation problems.

Children dosage: 20mg/kg/day in 3-4 divided doses

Children below 1 year: Body weight to be assured by physician.

2-5 years: One 5mls spoonful

6-12 years: Two 5mls spoonful

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.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Ibuflam can have side effects though not everyone gets them.

Non-specific allergic reactions and anaphylaxis,
Respiratory tract reactivity, e.g. asthma, aggravated asthma, bronchospasm, dyspnoea.

Various skin reactions, e.g. pruritis, urticaria, angioedema and more rarely exfoliative and bullous dermatoses (including epidermal necrolysis and erythema multiforme).
Report this or any other side effects to your doctor or pharmacist.

5. HOW TO STORE IBUFLAM:

Do not use Ibuflam after the expiry date stamped on the pack. The expiry date refers to the last day of the month.

Ibuflam should be stored in a cool place below 30°C, protected from direct sunlight and kept out of the sight and reach of children

Medicines should not be disposed off via wastewater or household waste. Ask your pharmacist how to dispose off medicines no longer required. These measures will help protect the environment.

6. FURTHER INFORMATION:

What Ibuflam contains

The active substances in Ibuflam preparations are Ibuprofen.

Ibuflam is a registered trademark of Biodeal Laboratories Ltd

Further information on summary of product characteristics can be obtained from the regulatory department of Biodeal Laboratories Ltd. regulatoryaffairs@biodealkenya.com

THIS PRODUCT CONTAIN LACTOSE

This product should be used on the advice of a doctor or pharmacist.

7. PRESENTATION:

Ibuflam is available as follows:

200mg: 10 x 10 in blister pack

400mg: 10 x 10 in blister packs,

Suspension: 60mls and 100ml in amber coloured bottles

Manufactured by:
Biodeal Laboratories Ltd.,
123,Lunga Lunga Road,
P.O Box 32040-00600,Nairobi,Kenya

Date approved:03/2023



**PATIENT INFORMATION LEAFLET:
IBUFLAM TABLETS/SUSPENSION:
{IBUPROFEN PREPARATIONS}**

Read this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor or pharmacist.
- Do not pass this medicine on to others. It may harm them, even if their symptoms are the same as yours.
- In order that this medicine works, it must be taken exactly as directed.
- Keep all medicines out of reach of children.
- If you want more information about this medicine ask your doctor or pharmacist.

- In this leaflet:
1. What Ibuflam is and what it is used for
 2. Before you use Ibuflam
 3. How to use Ibuflam
 4. Possible side effects
 5. How to store Ibuflam
 6. Further information
 7. Presentation

1. WHAT IS IBUFLAM AND WHAT IS IT USED FOR?

The name of the medicine is Ibuflam. The active ingredients are ibuprofen. Ibuflam is indicated for fever and relief of mild to moderate pain, used as an analgesic for relief of mild to moderate muscular pain, post-immunization pyrexia, symptomatic relief of headache, earache, dental pain and backache. It can also be used in minor injuries such as sprains and strains. It is effective in the relief of feverishness and symptoms of colds and influenza.

Each tablet contains: Ibuprofen 400mg BP
Ibuprofen 200mg BP
Each 5ml contains : Ibuprofen 100mg BP

2. BEFORE YOU USE IBUFLAM:

Do not use Ibuflam without medical advice:
If you have had an allergy to any of the ingredients in the past.
If you are on any other drugs.

3. HOW TO USE IBUFLAM:

Short term symptomatic treatment of fever and pain of mild to moderate intensity:

Adults and adolescents over 12 years (>40 kg)

One or two 200 mg tablets one to four times daily, as needed. An interval of at least 4-6 hours should be allowed between doses. Single doses exceeding 400 mg have not been shown to have any additional analgesic effect.

Dysmenorrhoea

One or two 200mg tablets one to three times daily, as needed. An interval of at least 4-6 hours should be allowed between doses. Treatment is started at the first sign of menstruation problems.

Children dosage: 20mg/kg/day in 3-4 divided doses

Children below 1 year: Body weight to be assured by physician.

2-5 years: One 5mls spoonful

6-12 years: Two 5mls spoonful

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.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Ibuflam can have side effects though not everyone gets them.

Non-specific allergic reactions and anaphylaxis,
Respiratory tract reactivity, e.g. asthma, aggravated asthma, bronchospasm, dyspnoea.

Various skin reactions, e.g. pruritis, urticaria, angioedema and more rarely exfoliative and bullous dermatoses (including epidermal necrolysis and erythema multiforme).
Report this or any other side effects to your doctor or pharmacist.

5. HOW TO STORE IBUFLAM:

Do not use Ibuflam after the expiry date stamped on the pack. The expiry date refers to the last day of the month.

Ibuflam should be stored in a cool place below 30°C, protected from direct sunlight and kept out of the sight and reach of children

Medicines should not be disposed off via wastewater or household waste. Ask your pharmacist how to dispose off medicines no longer required. These measures will help protect the environment.

6. FURTHER INFORMATION:

What Ibuflam contains

The active substances in Ibuflam preparations are Ibuprofen.

Ibuflam is a registered trademark of Biodeal Laboratories Ltd

Further information on summary of product characteristics can be obtained from the regulatory department of Biodeal Laboratories Ltd. regulatoryaffairs@biodealkenya.com

THIS PRODUCT CONTAIN LACTOSE

This product should be used on the advice of a doctor or pharmacist.

7. PRESENTATION:

Ibuflam is available as follows:

200mg: 10 x 10 in blister pack

400mg: 10 x 10 in blister packs,

Suspension: 60mls and 100ml in amber coloured bottles

Manufactured by:
Biodeal Laboratories Ltd.,
123,Lunga Lunga Road,
P.O Box 32040-00600,Nairobi,Kenya

Date approved:03/2023



**PATIENT INFORMATION LEAFLET:
IBUFLAM TABLETS/SUSPENSION:
{IBUPROFEN PREPARATIONS}**

Read this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor or pharmacist.
- Do not pass this medicine on to others. It may harm them, even if their symptoms are the same as yours.
- In order that this medicine works, it must be taken exactly as directed.
- Keep all medicines out of reach of children.
- If you want more information about this medicine ask your doctor or pharmacist.

- In this leaflet:
1. What Ibuflam is and what it is used for
 2. Before you use Ibuflam
 3. How to use Ibuflam
 4. Possible side effects
 5. How to store Ibuflam
 6. Further information
 7. Presentation

1. WHAT IS IBUFLAM AND WHAT IS IT USED FOR?

The name of the medicine is Ibuflam. The active ingredients are ibuprofen. Ibuflam is indicated for fever and relief of mild to moderate pain, used as an analgesic for relief of mild to moderate muscular pain, post-immunization pyrexia, symptomatic relief of headache, earache, dental pain and backache. It can also be used in minor injuries such as sprains and strains. It is effective in the relief of feverishness and symptoms of colds and influenza.

Each tablet contains: Ibuprofen 400mg BP
Ibuprofen 200mg BP
Each 5ml contains : Ibuprofen 100mg BP

2. BEFORE YOU USE IBUFLAM:

Do not use Ibuflam without medical advice:
If you have had an allergy to any of the ingredients in the past.
If you are on any other drugs.

3. HOW TO USE IBUFLAM:

Short term symptomatic treatment of fever and pain of mild to moderate intensity:

Adults and adolescents over 12 years (>40 kg)

One or two 200 mg tablets one to four times daily, as needed. An interval of at least 4-6 hours should be allowed between doses. Single doses exceeding 400 mg have not been shown to have any additional analgesic effect.

Dysmenorrhoea

One or two 200mg tablets one to three times daily, as needed. An interval of at least 4-6 hours should be allowed between doses. Treatment is started at the first sign of menstruation problems.

Children dosage: 20mg/kg/day in 3-4 divided doses

Children below 1 year: Body weight to be assured by physician.

2-5 years: One 5mls spoonful

6-12 years: Two 5mls spoonful

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.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Ibuflam can have side effects though not everyone gets them.

Non-specific allergic reactions and anaphylaxis,
Respiratory tract reactivity, e.g. asthma, aggravated asthma, bronchospasm, dyspnoea.

Various skin reactions, e.g. pruritis, urticaria, angioedema and more rarely exfoliative and bullous dermatoses (including epidermal necrolysis and erythema multiforme).
Report this or any other side effects to your doctor or pharmacist.

5. HOW TO STORE IBUFLAM:

Do not use Ibuflam after the expiry date stamped on the pack. The expiry date refers to the last day of the month.

Ibuflam should be stored in a cool place below 30°C, protected from direct sunlight and kept out of the sight and reach of children

Medicines should not be disposed off via wastewater or household waste. Ask your pharmacist how to dispose off medicines no longer required. These measures will help protect the environment.

6. FURTHER INFORMATION:

What Ibuflam contains

The active substances in Ibuflam preparations are Ibuprofen.

Ibuflam is a registered trademark of Biodeal Laboratories Ltd

Further information on summary of product characteristics can be obtained from the regulatory department of Biodeal Laboratories Ltd. regulatoryaffairs@biodealkenya.com

THIS PRODUCT CONTAIN LACTOSE

This product should be used on the advice of a doctor or pharmacist.

7. PRESENTATION:

Ibuflam is available as follows:

200mg: 10 x 10 in blister pack

400mg: 10 x 10 in blister packs,

Suspension: 60mls and 100ml in amber coloured bottles

Manufactured by:
Biodeal Laboratories Ltd.,
123,Lunga Lunga Road,
P.O Box 32040-00600,Nairobi,Kenya

Date approved:03/2023



**PATIENT INFORMATION LEAFLET:
IBUFLAM TABLETS/SUSPENSION:
{IBUPROFEN PREPARATIONS}**

Read this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor or pharmacist.
- Do not pass this medicine on to others. It may harm them, even if their symptoms are the same as yours.
- In order that this medicine works, it must be taken exactly as directed.
- Keep all medicines out of reach of children.
- If you want more information about this medicine ask your doctor or pharmacist.

- In this leaflet:
1. What Ibuflam is and what it is used for
 2. Before you use Ibuflam
 3. How to use Ibuflam
 4. Possible side effects
 5. How to store Ibuflam
 6. Further information
 7. Presentation

1. WHAT IS IBUFLAM AND WHAT IS IT USED FOR?

The name of the medicine is Ibuflam. The active ingredients are ibuprofen. Ibuflam is indicated for fever and relief of mild to moderate pain, used as an analgesic for relief of mild to moderate muscular pain, post-immunization pyrexia, symptomatic relief of headache, earache, dental pain and backache. It can also be used in minor injuries such as sprains and strains. It is effective in the relief of feverishness and symptoms of colds and influenza.

Each tablet contains: Ibuprofen 400mg BP
Ibuprofen 200mg BP
Each 5ml contains : Ibuprofen 100mg BP

2. BEFORE YOU USE IBUFLAM:

Do not use Ibuflam without medical advice:
If you have had an allergy to any of the ingredients in the past.
If you are on any other drugs.

3. HOW TO USE IBUFLAM:

Short term symptomatic treatment of fever and pain of mild to moderate intensity:

Adults and adolescents over 12 years (>40 kg)

One or two 200 mg tablets one to four times daily, as needed. An interval of at least 4-6 hours should be allowed between doses. Single doses exceeding 400 mg have not been shown to have any additional analgesic effect.

Dysmenorrhoea

One or two 200mg tablets one to three times daily, as needed. An interval of at least 4-6 hours should be allowed between doses. Treatment is started at the first sign of menstruation problems.

Children dosage: 20mg/kg/day in 3-4 divided doses

Children below 1 year: Body weight to be assured by physician.

2-5 years: One 5mls spoonful

6-12 years: Two 5mls spoonful

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.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Ibuflam can have side effects though not everyone gets them.

Non-specific allergic reactions and anaphylaxis,
Respiratory tract reactivity, e.g. asthma, aggravated asthma, bronchospasm, dyspnoea.

Various skin reactions, e.g. pruritis, urticaria, angioedema and more rarely exfoliative and bullous dermatoses (including epidermal necrolysis and erythema multiforme).
Report this or any other side effects to your doctor or pharmacist.

5. HOW TO STORE IBUFLAM:

Do not use Ibuflam after the expiry date stamped on the pack. The expiry date refers to the last day of the month.

Ibuflam should be stored in a cool place below 30°C, protected from direct sunlight and kept out of the sight and reach of children

Medicines should not be disposed off via wastewater or household waste. Ask your pharmacist how to dispose off medicines no longer required. These measures will help protect the environment.

6. FURTHER INFORMATION:

What Ibuflam contains

The active substances in Ibuflam preparations are Ibuprofen.

Ibuflam is a registered trademark of Biodeal Laboratories Ltd

Further information on summary of product characteristics can be obtained from the regulatory department of Biodeal Laboratories Ltd. regulatoryaffairs@biodealkenya.com

THIS PRODUCT CONTAIN LACTOSE

This product should be used on the advice of a doctor or pharmacist.

7. PRESENTATION:

Ibuflam is available as follows:

200mg: 10 x 10 in blister pack

400mg: 10 x 10 in blister packs,

Suspension: 60mls and 100ml in amber coloured bottles

Manufactured by:
Biodeal Laboratories Ltd.,
123,Lunga Lunga Road,
P.O Box 32040-00600,Nairobi,Kenya

Date approved:03/2023



**BIODEAL LABORATORIES LIMITED
NAIROBI, KENYA**

1.5.4 MOCK-UPS AND SPECIMEN

**APPLICATION DOSSIER FOR REGISTRATION
OF IBUFLAM 400MG TABLETS**