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

Read this leaflet carefully before you start taking this medicine

Honat Buffam is and what
 Before you use Ibuffam
 How to use Ibuffam
 Possible side effects
 How to store Ibuffam
 Further information

7. Presentation

LWHATISIBUFLAMAND WHATISIT 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 analgesis for relief of mild to moderate meascalar pain, post-immunization pyrexia, symptomatic relief of headache, carache, dental pain and backache. It can also be used in minor injuries such as sparins and strains. It is effective in the relief of feverishness and symptoms of colds and influenza.

Each tablet contains: Disported n 200mg BP.

Each 5ml contains: Ibuprofen 200mg BP.

2. BEFORE VOU USE IDUFLAM:

Do not use Ibuflam without meetical advice:

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 treatme. ent of fever and pain of mild to moderate intensity:

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 nanlegisc of fetc.

Dysmenorrhoea
One or two 200 mg 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

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 meantrainton problems.

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

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Children bedaw I year: Body weight to be assured by physician.

2-5 years: (no 5 mis spoonful

6-12 years: (no 5 mis spoonful

7-12 years: (no 5 mis spoonful

8-12 years: (no 5 mis spoonful

9-12 years: (no 5 mis spoonful

Various skin reactions, e.g. prurtis, urticaria, angioedema and more rarely exfoliative and bullous dermatoses (including epidermal necrolysis and expertmen multiformse).

Report this or any other side effects to your doctor or proflamacist.

S. HOW TOST (DORE IBUFLAM):

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

Bullam 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 be protect the environment.

6. FURTHER INFORMATION:

What Bullam contains

What Ibnflam contains
The active substances in Burlam 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.
regulatory/affairs/abiodeal/denvay.com
THIS PRODUCT CONTAIN LACTOSE

THIS PRODUCT CONTAIN LACTOSE
This product should be used on the advice of a doctor or pharmacist.
7.PRESENTATION:
Blufflam is available as follows:
200mg: 10 x 10 in blister pack.
400mg: 10 x 10 in blister pack.
Suspension: 60mls and 100ml in amber coloured bottles

Mr.



Manufactured by: Biodeal Laboratories Ltd.,

123,Lunga Lunga Road, P.O Box 32040-00600,Nairobi,Kenya Date approved:03/2023

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-If you have any further questions, please ask your doctor or pharmacist.

-Do not pass this medicine ont to others. I 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.

-Repeal medicines out of reach of children.

-If you want more information about this medicine ask your doctor or pharmacist.

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LWHATISIBUFLAMAND WHATISIT USED FOR?

The name of the medicine is Ibudian. The active ingredients are ibuprofen, Ibudiam 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, carache, dental pain and backache. It can also be used in minor injuries such as sportians and strains. It is effective in the relief of feverishness and symptoms of colds and influenza.

Each tablet contains: Ibuprofen 200mg BP

Libuprofin 200mg BP

Each Sml contains: I subprofin 100mg BP.

2. BEFORE YOU USE BUFLAM:

Do not use buffer any without medical advice.

ADDEFORE TOU 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. HOWTO USE IBUFLAM:

If you are on any other drugs.

3. HOW TO USE IBUTELAN:
Short term symptomatic treatment of fever and pain of mild to moderate intensity:
Adults and adolescents over 12 years (2-40 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 managesic effect.

Dysmcorribea
One or two 200 mg 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 menstration 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: (no 5 mis spoonful
Etderyt; The deldryt 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, Buhfam can have side effects though not everyone gets them. 4. POSSIBLÉ SIDE EFFECTS
Like all medicines, Ibuflam can have side effects though not everyone gets them.
Non-specific alliegie reactions and anaphylaxis,
Respiratory tract reactivity, e.g. asthma, aggravated asthma, bronchospasam, dyspnoea.
Various skin reactions, e.g. prutist, surtiearia, 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 TOSTORE IBUFLAM:
Do not use bludlam after the expirity data etamocal.

N.H.W. LINLUKE. IBLFLANI:
Do not use bludlan after the expiry date stamped on the pack. The expiry date refers to the last day of the month.
Bullam 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 prote the environment.
6. FURTHER INFORMATION:

What Ibuffam contains
The active substances in Ibuffam preparations are Ibuprofen.
Ibuffam 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.
regulatoryaffamicabloidealkuva.com
THIS PRODUCT CONTAIN LACTOSE

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

7. PRESENTATION:

Blufflam is available as follows:
200mg: 10 x 10 imbister pack.
400mg: 10 x 10 imbister pack,
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}

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- If you have any further questions, please ask your doctor or pharmacist.
- Do not pass this medicine no 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:
- I What I budlann is and what it is used for

What Ibuffam is and what
 Before you use Ibuffam
 How to use Ibuffam
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7. Presentation
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Each allel contains: Bhoprofen 400mg BP
10. Beach some contains: Bhoprofen 400mg BP
10. Beach some contains and the strains of the strains and strains. It is effective in the relief of feverishness and symptoms of colds and influenza.

Each salle contains: Bhoprofen 400mg BP
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Due 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

Dysmortnee
One or two 200mg tablets one to three times oam, ...
first sign of menstruation problems.
Children dosage: Zümgkgeday in 3-4 divided doses
Children below 1 year: Body weight to be assured by physician.
2-5-years: One Simils spoonful
6-12-years: Two Simils spoonful
6-12-years

function is impaired, dosage should be assessed individually.

4. POSSIBLESDIE EFFECTS

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

Non-specific allergic reactions and anaphy laxis.

Respiratory much reactivity, e.g. admina, agent varied asthma, bronchospasim, dyspnoea.

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

5. HOW TOSTORE IBUTEAN:

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6. FURTHER INFORMATION:

What Bulfann contains

The active substances in lbulfam preparations are lbuprofen.

Bulfann is registered trademark of Biodeal Laboratories Ltd.

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regulatoryaffairs@biodealkenya.com.
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Read this leaflet carefully before you start taking this medicine.

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- 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.

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- What but had an is and what it is used for a Before you use that it is used for a Before you use that if an are the same as yours.

Before you use Ibuflam
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7. Presentation
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Do not use Ibuflam without medical advice:
If you have had an allergy to any of the ingredients in the past.

3. HOW TO USE IBUFLAM:

5. HOW TO USE IB CPLANT:

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

Adults and adolescents over 12 years (>40 kg)

One or two 200 mg labels one to feur 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.

Descenorables

Dysmenorrhoea

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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 menstratuation problems.

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Children dosage: 20mg/kg/day in 3-4 divided doses
Children dosage: 30mg/kg/day in 3-4 divided doses
Children dosage: 30mg

Do not use Itudian after the expiry date stamped on the pack. The expiry date refers to the last day of the month. Ibudian 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 measures will be protect the environment.

6.FURTHER INFORMATION:

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What Ibulam contains
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Buffanis available as follows:
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# BIODEAL LABORATORIES LIMITED NAIROBI, KENYA

## 1.5.4 MOCK-UPS AND SPECIMEN

APPLICATION DOSSIER FOR REGISTRATION OF IBUFLAM 400MG TABLETS