### REGIONAL ADMINISTRATIVE INFORMATION

| Product: Brofix Ophthalmic Solution |  

1.3.3.2 English Leaflet

Enclosed Revised PIL
Read all of this leaflet carefully before you start using Brofix™.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.

1. What Brofix™ is and what it is used for

Brofix™ contains bromfenac and belongs to a group of medicines called nonsteroidal anti-inflammatory drops (NSAIDs). It works by blocking certain substances involved in pain and inflammation. Therefore, Brofix™ is used to reduce eye inflammation following cataract surgery in adults.

2. Before you use Brofix™

- Do not use Brofix™
  - if you are allergic (hypersensitive) to bromfenac or to any of the other ingredients of Brofix™ (see section 6 “Further information”).
  - if you have experienced asthma, skin allergy or immediate inflammation of your nose when using other NSAIDs. Examples of NSAIDs are: acetylsalicylic acid, ibuprofen, ketoprofen, diclofenac.

- Take special care with Brofix™
  - if you are using topical steroids (e.g. cortisone), as this may cause unwanted side effects.
  - if you have a bleeding disorder (e.g. haemophilia) or have had them in the past, or you are taking other medicines which may prolong bleeding time.
  - if you have eye problems (e.g. dry eye syndrome, corneal problems).
  - if you have had diabetes.
  - if you have rheumatoid arthritis.
  - if you have had repeated eye surgery within a short period of time.

Children and adolescents

Brofix™ should not be used in children and adolescents.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without prescription.

3. How to use Brofix™

- Do not use more Brofix™ than you should.
- Use a single dose as soon as you remember. If it is almost time for the next dose, leave out the missed dose.
- Continue with the next regularly scheduled dose. Do not use a double dose to make up for a forgotten dose.
- If you stop using Brofix™
  - Do not stop using Brofix™ without speaking to your doctor or pharmacist.

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

4. Possible side effects

Like all medicines, Brofix™ can cause side effects, although not everybody gets them.

If you experience decreased or blurred vision the week after the end of treatment, you should contact your doctor immediately.

If you notice any of the following side effects while using the drops, contact your doctor immediately:

- This medicine has been prescribed for you. Do not take it for anyone else even if you think they have the same symptoms.

5. How to store Brofix™

- Keep out of the reach of sight of children.
- Do not store above 30 ºC.
- Do not use Brofix™ after the expiry date which is stated on the bottle and outer carton after “EXP”.
- Discard after 30 days of opening.
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Further information

What Brofix™ contains

Each ml contains:

Active Ingredients: 1.035mg bromfenac sodium

Other GCC States:

- Oman
  - Website: www.sfda.gov.om/npc
  - Toll free phone: 8002490000

Other GCC States:

- Oman
  - Website: www.sfda.gov.om/npc
  - Toll free phone: 8002490000
  - E-mail: epc@sfda.gov.om

For further information, please contact the relevant competent authority.

The leaflet was last approved in 12/2014.

Version number: 0

THIS IS A MEDICAMENT

- Medication is a product that affects your health, and its consumption contrary to instructions is dangerous for your health.
- Follow strictly the doctor's prescription, the method of use and the instructions from the pharmacist who sold the medication.
- The doctor and the pharmacist are experts in medicine, its benefits and risks.
- Do not buy or use a medicine that is not prescribed for you.
- Do not repeat the same prescription without consulting your doctor.

Keep all medications out of the reach of children.
1.3.3.2 **English Leaflet**

Enclosed OLD PIL
**1. What Brofix™ is and what it is used for**

Brofix™ contains bromfenac and belongs to a group of medicines known as non-steroidal anti-inflammatory drugs (NSAIDs). It works by blocking certain substances involved in causing inflammation. Therefore, Brofix™ is used to reduce eye inflammation following cataract surgery in adults.

**2. Before you use Brofix™**

Do not use Brofix™
- if you are allergic (hypersensitive) to bromfenac or to any of the other ingredients of Brofix™ (see section 6 “Further information”).
- if you have experienced asthma, skin allergy or intense inflammation in your nose when using NSAIDs. Examples of NSAIDs are: acetylsalicylic acid, ibuprofen, ketoprofen, diclofenac.

Take special care with Brofix™
- if you are using topical steroids (e.g. cortisone), as this may cause unwanted side effects.
- if you have visual problems (e.g. halmopilia) or have had them in the past, or you are taking other medicine which may prolong bleeding time.
- if you have eye problems (e.g. dry eye syndrome, corneal problems).
- if you have diabetes.
- if you have rheumatoid arthritis.
- if you have repeated eye surgery within a short period of time.

Children and adolescents
Brofix™ should not be used in children and adolescents.

Taking other medicines
Please tell your doctor or pharmacist if you are taking any other medicine, including medicines obtained without prescription.

**3. Dose and duration of treatment**

Your vision may be blurred for a short time after using Brofix™. If the eye sensation blurred vision occurs using Brofix™, do not drive or use machines until your vision is clear.

Important information about some of the ingredients of Brofix™
Brofix™ contains sodium sulphate which may cause allergic reactions.

Brofix™ contains benzalkonium chloride, a preservative which may cause eye irritation.

Do not use Brofix™ while wearing contact lenses, since the presence of benzalkonium chloride is known to discolour them. Additionally, wearing contact lenses is not recommended after cataract surgery. Therefore, do not wear contact lenses whilst using Brofix™.

**4. How to use Brofix™**

Always use Brofix™ exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

**5. How to store Brofix™**

Keep out of the reach and sight of children.

**6. Further information**

**What Brofix™ contains**
Each ml contains:
- Bromfenac: active principle
- Sodium sulphate
- Polysorbate 80
- Sodium yesun"anhydrous
- Povidone
- Benzalkonium chloride
- Boric acid
- Sodium chloride
- Water for injection
- Disodium hydrogen carbonate
- Potassium chloride
- Sodium hydroxide
- Hydrochloric acid
- Benzyl alcohol
- Parabens

**What Brofix™ looks like and contents of the pack**
Brofix™ is a quality product manufactured by:

Ophthalmics

**P.O.Box 6267 Jeddah - 21442- Saudi Arabia**

If you forget to use Brofix™
Use a single dose as soon as you remember. If it is almost time for the next dose, leave out the missed dose. Continue with the next regularly scheduled dose. Do not use a double dose to make up for a forgotten dose.

If you stop using Brofix™
Do not stop using Brofix™ without speaking to your doctor.

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

**4. Possible side effects**

Like all medicines, Brofix™ can cause side effects, although not everybody gets them.

If you experience decreased or blurred vision the week after the end of treatment, you should contact your doctor immediately. If you notice any of the following side effects while using the drops, contact your doctor immediately. Uncommon side effects (Affects 1 to 10 users in 10,000):
- Foreign body sensation in the eye, redness and inflammation of the eye, damage and inflammation of the surface of the eye, eye discharge, itching, irritation or pain of the eye, swelling or bleeding of the eyelid, impaired vision due to inflammation, floaters or moving spots before the eyes or dimensions vision that can indicate bleeding or damage of the back of the eye (retina), ocular discoloration, sensitivity to light, reduced or blurred vision, swelling of the face, conjunctival bleeding or red nose.

Rare side effects (Affects 1 to 10 users in 10,000):
- Damage of the eye surface, redness of the eye, asthma.
- If any of the side effects gets serious or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

**5. How to store Brofix™**
Keep out of the reach and sight of children.

Do not store above 30°C.
Do not use Brofix™ after the expiry date which is stated on the bottle and outer container after “EXP.” Once opened the drops should not be used for longer than 1 month.

Do not use a double dose to make up for a forgotten dose. Do not stop using Brofix™ without speaking to your doctor.

If you stop using Brofix™
Do not use a double dose to make up for a forgotten dose. Continue with the next regularly scheduled dose. Do not use a double dose to make up for a forgotten dose.

**5. How to store Brofix™**

**6. Further information**

**What Brofix™ contains**
Each ml contains:
- Bromfenac: active principle
- Sodium sulphate equivalent to 0.9 mg bromfenac free acid.
- Other ingredients are benzalkonium chloride, boric acid, sodium tetaborate (borax), disodium edetate, sodium hydroxide, borate 80, sodium sulphate, hydroxy-20, sodium hydroxy (to adjust pH) and water for injection.

**What Brofix™ looks like and contents of the pack**

Brofix™ is a quality product manufactured by:

Ophthalmics

**P.O.Box 6267 Jeddah - 21442- Saudi Arabia**

**THIS IS A MEDICAMENT**

- **Medicament is a product that affects your health, and its consumption contrary to instructions is dangerous for your health.**
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicine.
- Do not be subjected to any form of treatment prescribed by anyone other than your doctor.
- Do not repeat any prescription without consulting your doctor.
- Keep all medicines out of the reach of children.

**Council of Arab Health Ministers & Union of Arab Pharmacists**

**Ophthalmics**

**Brofix™ is a quality product manufactured by:**
1.3.3.2 English Leaflet

Enclosed Old PIL
Do not use more than the recommended dose.

- If you are allergic (hypersensitive) to bromfenac or to any of the other ingredients of Brofix™ (see section 6 “Further information”)
- If you have experienced asthma, skin allergy or intense inflammation in your nose when using other NSAIDs. Examples of NSAIDs are: acetylsalicylic acid, ibuprofen, ketoprofen, diclofenac.
- Take special care with Brofix™
  - if you are using topical steroids (e.g. cortisone), as this may cause unwanted side effects.
  - if you have a history of glaucoma (e.g. harmelophila) or have had them in the past, or you are taking other medicines which may prolong bleeding time.
  - if you have eye problems (e.g. dry eye syndrome, corneal problems).
  - if you have diabetes.
  - if you have rheumatoid arthritis.
  - if you have ever had cataract surgery.

Administration

- Do not use the drops if you are not sure.
- Store your cataract surgery. Continue the drops through the first 2 weeks after your surgery.
- If you do not use Brofix™ longer than 2 weeks.
- If you have repeated eye surgery within a short period of time.
- If you have experience decreased or blurred vision the week after the end of treatment, you should contact your doctor immediately.
- If you use any of the following side effects while using the drops, contact your doctor immediately:
  - Inability to focus, blurred vision, spots before the eyes or diminishing vision that can appear after using the drops.
  - Damage of the eye surface, redness and inflammation of the eye, damage and inflammation of the surface of the eye, eye discharge, itching, irritation or pain of the eye, swelling or bleeding of the eyelid, impaired vision due to inflammation, fluctuates or moving spots before the eyes or diminishing vision that can indicate bleeding or damage of the back of the eye (retina), ocular discomfort, sensitivity to light, bright or blurred vision, swelling of the face, conjunctival bleeding or runny nose.
- Rare side effects (Affects 1 to 10 users in 10,000)
  - Damage to the eye surface, redness of the eye, asthma.
  - If any of the side effects gets serious or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. How to store Brofix™

Keep out of the reach of children and animals.

- Do not store above 30 °C.
- Do not use Brofix™ after the expiry date which is stated on the bottle and must not be longer than 2 years.
- Once opened the drops should not be used for longer than 1 month.
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Further information

What Brofix™ contains

Each ml contains:

- Active ingredients: 1.05mg bromfenac sodium sesquicyanate equivalent to 0.9 mg bromfenac free acid.
- Other ingredients are benzalkonium chloride, boric acid, sodium tetraborate (Borax), disodium edetate, sodium hydroxide 9N (to adjust pH), water for injection.

What Brofix™ looks like and contents of the pack

Brofix™ Eye Drops is a clear yellow solution. Brofix™ Eye Drops, 5 ml filled in LEPO eye drop bottles.

Marketing Authorisation Holder and Manufacturer

Jamjoom Pharmaceuticals Co., Ltd., Jeddah, Saudi Arabia.

Website: www.2-6-081111. Fax: +966-11-205-7662
E-mail: npc.dru@gdf.gov.sa
Website: www.jamjoompharma.com
National Pharmacovigilance Center (NPC)
- Other GCC States:
  - Please contact the relevant competent authority. This leaflet was last approved in 05/2013. Version number 01.

This is a Medicament

- Medicament is a product that affects your health, and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicine.
- The doctor and the pharmacist are experts in medicine, its benefits and risks.
- Do not buy or take the medicine prescribed for you.
- Do not repeat the same prescription without consulting your doctor.

Keep all medicines out of the reach of children.

THIS IS A MEDICAMENT

- Medicament is a product that affects your health, and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicine.
- The doctor and the pharmacist are experts in medicine, its benefits and risks.
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