What is this leaflet:

- This leaflet provides information about Vistamethasone Drops.

Do not use in your ears if you:

- Have a hole in your ear drum
- Have any other ear infection
- Have an allergy to betamethasone or any of the other ingredients

Do not use in your eyes if you:

- Have an eye infection that is producing pus
- Have an eye infection that is producing a fluid
- Have a fungal infection of the eye
- Have a viral infection of the eye
- Have an eye injury
- Are wearing soft contact lenses
- Have a hole in your eye(s)

Do not use Vistamethasone Drops:

- If you are pregnant or breast-feeding
- If you are allergic (hypersensitive) to betamethasone or any of the other ingredients
- If you have dry eyes or disorders of the cornea
- If you have a fungal or viral infection of your eye
- If you have any other eye infection

Do not use Vistamethasone Drops if you:

- Use the outer cap on the bottle, trying not to touch the applicator tip with anything, including your fingers
- Wash your hands as soon as you have used the drops

Instructions for use in the nose:

1. Wash your hands well before use.
2. Remove the outer cap on the bottle.
3. Tilt your head back and pour into each nostril drop by drop.
4. Replace the outer cap on the bottle, trying not to touch the applicator tip with anything, including your fingers.
5. Wash your hands.

Instructions for use in the ear:

1. Wash your hands well before use.
2. Remove the outer cap on the bottle.
3. For use in the nose:
   - Tilt your head back and pour into each nostril drop by drop.
   - Replace the outer cap on the bottle, trying not to touch the applicator tip with anything, including your fingers.
   - Wash your hands.
4. For use in the eye:
   - Tilt your head back and look up at the ceiling.
   - Pull the lower lid of the eye out to form a small pocket between your eyelid and your eye.
   - Hold the container between the thumb and middle finger of the other hand, turn the bottle upside down near to your eye, try not to touch your eye with the nozzle.
   - Apply enough pressure to the container to release one or two drops, or as directed by your doctor.
   - Blink your eye a few times.
5. If you think that you have missed your eye, then insert another drop.
6. Repeat steps 1-5 in the other ear, if you have been told to use Vistamethasone Drops in both ears.
7. If you need to use both Vistamethasone Drops for as long as your doctor has instructed.
8. Your treatment is helping your condition, even if you have not noticed a difference in how you feel. Should you need to stop taking your medicine, your doctor will advise you how to do this.

3. How to use Vistamethasone Drops:

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

How much to use:

For adults, the elderly and children:

For use in the eye:

The usual starting dose is two or three drops put into the eye every three to four hours. Your doctor may reduce the dose once the condition of your eye has begun to improve.

For use in the ear:

The usual starting dose is two or three drops put into the ear every three to four hours. You may require a dosage increase if you have a prescription to use Vistamethasone Drops for as long as your doctor has instructed.

For use in the nose:

The usual starting dose is one or two drops to be put into the eye every two hours. Your doctor may reduce the dose once the condition of your eye has begun to improve.

Instructions for use:

- For use in the eye:
  - Tilt your head back and look up at the ceiling.
  - Pull the lower lid of the eye out to form a small pocket between your eyelid and your eye.
  - Hold the container between the thumb and middle finger of the other hand, turn the bottle upside down near to your eye, try not to touch your eye with the nozzle.
  - Apply enough pressure to the container to release one or two drops, or as directed by your doctor.
  - Blink your eyes a few times.
  - If you think that you have missed your eye, then insert another drop.
  - Repeat steps 1-5 in the other eye, if you have been told to use Vistamethasone Drops in both ears.
  - Replace the outer cap on the bottle, trying not to touch the applicator tip with anything, including the eye or your fingers.
  - Wash your hands.

For use in the nose:

- Tilt your head back and look up at the ceiling.
- Pull the lower lid of the eye out to form a small pocket between your eyelid and your eye.
- Hold the container between the thumb and middle finger of the other hand, turn the bottle upside down near to your eye, try not to touch your eye with the nozzle.
- Apply enough pressure to the container to release one or two drops, or as directed by your doctor.
- Blink your eyes a few times.
- If you think that you have missed your eye, then insert another drop.
- Repeat steps 1-5 in the other ear, if you have been told to use Vistamethasone Drops in both ears.
- Replace the outer cap on the bottle, trying not to touch the applicator tip with anything, including the eye or your fingers.
- Wash your hands.

Instructions for use in the ear:

- Wash your hands well before use.
- Remove the outer cap on the bottle.
- Tilt your head back and pour into each nostril drop by drop.
- Replace the outer cap on the bottle, trying not to touch the applicator tip with anything, including your fingers.
- Wash your hands.

4. Possible side effects:

Like all medicines, this medicine can cause side effects, although not everybody gets them.

If you experience any of the following side effects you should tell your doctor directly:

- Difficulty in breathing with or without swelling of the face, lips, tongue and/or throat
- Swelling of the face, lips, tongue and/or throat, which may cause difficulty in swallowing
- Severe itching of the skin (with raised lumps).
- Other possible side effects include:
  - Irritation, burning, itching and stinging in the area. This may occur after treatment has stopped.
  - Raised pressure in the eye (cataracts), it is therefore advisable that the lens of the eye is checked frequently during use of this medicine.
  - If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. How to store Vistamethasone Drops:

- Keep this medicine out of the sight and reach of children. Make sure the container is properly closed after each use.
- Store Vistamethasone Drops in its original container away from direct light. Store below 25°C.
- Do not use this medicine after the expiry date shown on the label. The expiry date refers to the last day of that month.
- Dispose of this medicine 4 weeks after opening.

- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use.

6. Content of the pack and other information:

What Vistamethasone Drops contain:

The active substance is betamethasone sodium phosphate 0.1% w/v.

The other ingredients are benzalkonium chloride solution, disodium edetate, sodium phosphate and purified water.

What Vistamethasone Drops look like and contain:

Vistamethasone Drops are a clear, colourless and sterile solution supplied in a plastic dropper bottle with a cap. Each bottle contains 5 or 10ml of the solution.

Marketing Authorisation Holder:

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If you would like any more information, or would like the leaflet in a different format, please contact Medical Information at the above address.

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