INDOMETACIN PIL 03.02.2014:Layout 1  2/4/14  1:56 PM  Page 1

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In this leaflet:
1. What Indometacin is and what it is used for
2. What you need to know before you take Indometacin
3. How to take Indometacin Capsules
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5. How to store Indometacin Capsules
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1. WHAT INDOMETACIN IS AND WHAT IT IS USED FOR

- Indometacin belongs to the group of medicine known as non-steroidal anti-inflammatory drugs or NSAI D's.
- Indometacin is used for degenerative hip disease, ankylosing spondylitis, rheumatoid arthritis, to reduce swelling, muscular pain, low back pain, pain following bone or joint surgery, gout and period pain.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE INDOMETACIN

Do not take Indometacin if you:
- think you are pregnant or you are planning to get pregnant or are breastfeeding.
- have polyps in your nose, associated with itching, nettle rash, wheezing or swelling of the face, lips, tongue and throat. Difficulties in swallowing or breathing.
- are allergic to Indometacin or any of the other ingredients in this medicine (listed in section 6).
- are allergic (hypersensitive) to aspirin, ibuprofen or other NSAIDs.
- are taking other NSAIDs (e.g. naproxen) including COX II inhibitors (e.g. celecoxib).
- have, or have ever had, peptic ulceration (ulcer in your stomach or duodenum), or bleeding in your digestive tract, suffer from persistent stomach problem. Symptoms may include vomiting particles that look like coffee-grounds, black tarry stools and blood in your faeces (stools/ motions).
- have severe liver, kidney or heart problems

Warnings and precautions

Talk to your doctor or pharmacist before taking Indometacin if you:
- are epileptic, have Parkinson's disease, psychiatric problem
- have high blood pressure, heart disease or have tendency to fluid retention
- are being treated for infection (or sepsis) or have a fever
- suffer from asthma.
- Suffer from any disease of the bowel such as Crohn's disease or ulcerative colitis
- Currently have an infection (treated or not) or are receiving treatment with live vaccines
- Suffer with systemic lupus erythematosus (SLE) or any other connective tissue disorder. Are due to have an operation
- suffer from kidney or liver disease, diabetes or heart failure
- have problem with blood clotting
- have rheumatoid arthritis
- have a bleeding or blood clotting disorder
- have diabetes, suffer from peripheral arterial disease
- have a decreased amount of fluid around the cells of the body (extracellular volume depletion)
- are allergic to Indometacin or any of the other ingredients of this medicine (listed in section 6).

If you are elderly or you have previously had stomach ulcers, you have a higher risk of getting side effects, especially from the stomach. Your doctor should therefore prescribe the lowest dose that gives you sufficient relief. If you experience any unusual symptoms from the stomach, you must tell your doctor about it.

Key points: Medicines such as Indometacin 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

If you have heart problems, previous stroke or think that 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.

Children: Indometacin capsules must not be used in children.

Other medicines and Indometacin

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. Indometacin capsules may alter the results of some blood or urine tests. If you see another doctor or go in to hospital, let them know what medicine you are taking.

You should discuss the matter with your doctor if you are taking any of the following:
- aspirin or other non-steroidal anti-inflammatory drugs or diffusional for pain relief
- corticosteroids, which are drugs given to treat a variety of conditions such as allergies and hormone imbalance
- anticoagulants such as warfarin to prevent blood clots
- certain drugs for depression called selective serotonin reuptake inhibitors (SSRI)
- medicines such as acetylsalicylic acid to prevent platelet clumping
- quinolone antibiotics (such as ciprofloxacin)
- lithium or haloperidol (psychiatric medicines)
- antiviral medicines (such as zidovudine or ritonavir)
- phenytoin (for epilepsy)
- diazepam (for anxiety, difficulty sleeping, alcohol withdrawal, seizures and muscle spasm)
- medicines used to treat high blood pressure such as beta blockers (e.g. atenolol), alpha blockers (e.g. prazosin), ACE inhibitors (e.g. lisinopril), angiotensin II receptor antagonists (e.g. valsartan), hydralazine or nifedipine
- sulphonylureas (used to treat diabetes)
- cardiac glycosides (used to treat heart conditions eg digoxin)
- ciclosporin or tacrolimus (immune system medicine), methotrexate (used to treat some cancers, severe psoriasis and severe rheumatoid arthritis)
- mifepristone (used to induce abortion)
- desmopressin (for diabetes insipidus and frequent urination during the night)
- diuretics (water tablets) such as triamterene, thiazides (e.g. bendroflumethiazide) or furosemide
- baclofen (a muscle relaxant), probenecid (for gout)
- pentoxifylline (for blood vessel disease and leg ulcers)
- tiludronic acid (for Paget's disease of bone).

If any of these applies to you please tell your doctor immediately.

Pregnancy, breast-feeding and fertility

Indometacin Capsules may make it more difficult to become pregnant. If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines

Indometacin may cause dizziness, drowsiness, fatigue and visual disturbance are possible in some people, if it happens do not drive or operate machinery.

Tests

Your doctor may want to carry out tests to monitor your kidney and liver function, the levels of blood cells and the effects on your stomach and intestines (especially if you are elderly). If you have or have had a history of high blood pressure or heart failure your doctor may also want to monitor you. If you have rheumatoid arthritis you may be advised to have regular eye tests to check your sight.

Surgery

If you are about to have, or have recently had surgery, please contact your doctor before using this medicine.

Indometacin contains Lactose:

Lactose (a type of sugar): If you have been told that you have intolerance to some sugars, contact your doctor before taking this medicine.

3. HOW TO TAKE INDOMETACIN

Always take 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.
It is important to take your medicine with food or with an antacid; this will help you to prevent any stomach disturbance. The recommended dose is:

**Adults:**
- **Acute rheumatoid arthritis:** initially 25mg two or three times a day.
- **Chronic joint disorders:**
  - **Adults:** The recommended dose is up to a maximum of 200mg a day.
- **Acute muscle and bone disorders:** initially 50mg two or three times a day for 10-14 days. Your doctor will decide on the best dose for you, depending on the severity of your condition.
- **Lower back pain:** 50mg two or three times a day for 5-10 days. Your doctor will decide on the best dose for you, depending on the severity of your condition.
- **Acute attack of gout:** 100-150mg a day in divided doses, to be taken until symptoms decrease.
- **After muscle or bone surgery:** 100mg three or four times a day for 5-10 days. Your doctor will decide on the best dose for you, depending on the severity of your condition.

**Elderly:** If you are elderly, your doctor will give you the lowest effective dose for the shortest amount of time.

**Children:** Indometacin is not recommended for children.

If you take more Indometacin than you should:
- If you or anyone else has swallowed a lot of the capsules all together contact your nearest hospital casualty department or doctor immediately. Take your medication with you.
- **Symptoms of overdose** are headache, feeling or being sick (nausea/vomiting), stomach pain, bleeding in the stomach or intestines, diarrhoea, disorientation, excitement, coma, drowsiness, dizziness, ringing in the ears, fading of vision, fainting, mental confusion, feeling tired, numbness, burning, prickling, itching, or tingling sensation of the skin, fits or seizures, kidney failure, liver damage.

If you forget to take Indometacin:
- If you miss one dose of your medicine take one as soon as you remember unless it is nearly time to take the next one. Do not take a double dose to make up for a forgotten dose. Take the remaining doses at the correct time.

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

### 4. POSSIBLE SIDE EFFECTS

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

**The most common side effects** are headache, dizziness and indigestion.

**Serious side effects** can be:
- If you suffer from any of the following at any time during your treatment **STOP TAKING** the medicine and seek immediate medical help:
  - pass blood in your faeces (stools/motions), pass black tarry stools, vomit any blood or dark particles that look like coffee grounds;
  - allergic reactions - difficulty breathing or swallowing, asthma, sudden decrease in blood pressure, swelling of the face, lips, tongue or throat.

**STOP TAKING** the medicine and tell your doctor if you experience:
- **Indigestion** or heartburn, abdominal pain (pains in your stomach) or other abnormal stomach symptoms.
- **Skin reactions** such as itching, pale or red irregular raised patches with severe itching (hives), disorder characterised by blood spots, bruising and discoloration of the skin (purpura), blisters or skin that is red, flaky or peeling such as severe rash involving reddening, peeling and swelling of the skin that resembles severe burns (toxic epidermal necrolysis), circular, irregular red patches on the skin of the hands and arms (erythema multiforme), severe form of skin rash with flushing, fever, blisters or ulcers (Stevens Johnson syndrome)
- **Aseptic meningitis** can occur in some patients. This may show combination of symptoms such as headache, fever, stiff neck and tiredness.

Medicines such as Indometacin may be associated with a small increased risk of heart attack ("myocardial infarction") or stroke.

**Other side effects** - If you experience any of the following other side effects contact your doctor or pharmacist:
- **Effects on the nervous system:** Fatigue, drowsiness, dizziness, headaches, convulsions, sleeplessness, fainting, coma, loss of sensation, lightheadedness, vertigo, tiredness, anxiety, speech problem, confusion, mental disturbances and rarely pins and needles, muscle weakness and involuntary muscle movements.
- **Effects on the stomach, intestine and colon:** Abdominal pain or discomfort, loss of appetite, nausea, vomiting, constipation, diarrhoea, flatulence, inflammation of mouth or gums or worsening of these conditions and ulceration of intestine which can cause bleeding and worsening of ulcerative colitis and ulcer in and or bleeding from the gut.
- **Effects on the skin:** Inflammation of the pancreas causing pain and tenderness in the abdomen and back (pancreatitis), intestinal strictures and regional ileitis have been rarely reported.
- **Effects on the eye:** Pain in the eye or other vision disturbances, infrequently blurred or double vision.
- **Effects on the ear:** Ringing in the ear or other hearing disturbance (tinnitus).
- **Effects on the blood:** Small purple red spots, nosebleeds, bruising, disorder characterised by blood spots, blood clotting throughout the body, disturbance of blood count, reduction in blood cell production by the bone marrow. If you notice increased bruising, nosebleeds, sore throats, infections, excessive tiredness, breathlessness on exertion, or abnormal paleness of the skin, you should tell your doctor who may want you to have a blood test.
- **Effects on the heart:** High or low blood pressure, increased or decreased blood pressure, increased or irregular heart rate, chest pain, heart failure and abnormal heart burn.
- **Effects on the liver:** Inflammation of the liver, jaundice (yellow skin or eyes).
- **Effects on the kidney:** Inflammation, disease or failure, blood or protein in the urine and increase in blood urea.
- **Effects on the Skin:** Inflammation of blood vessels, sensitivity to sunlight or artificial light (e.g. sun beds), tender red lumps usually on the legs (erythema nodosum), hair loss, sweating, worsening of psoriasis (itchy scaly pink patches on the elbows, knees, scalp and other parts of the body)
- **Effects on reproductive system:** Bleeding from the vagina, breast enlargement or tenderness, enlarged breasts in men.
- **Other effects:** Increased level of sugar in the blood, high level of potassium in the blood.

**Reporting of side effects:** If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard. By reporting side effects you can help provide more information on the safety of this medicine.

### 5. HOW TO STORE INDOMETACIN

Keep this medicine out of the sight and reach of children.
- **This medicine should not be used after the expiry date stated on the pack.**
- **Store in a cool and dry place, below 30°C.**
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

### 6. CONTENTS OF THE PACK AND OTHER INFORMATION

**What Indometacin Capsules contain:**
- **The active substance** is 25mg of the active ingredient Indometacin BP.
- **The other ingredients** are:
  - Lactose, colloidal silicon dioxide and sodium lauryl sulphate.

**What Indometacin Capsules looks like and contents of pack:**
- **Ivory coloured, hard, gelatine capsules, size 3. Overprinted '25' and 'PHARMVIT'**.

**Pack sizes of Indometacin 25mg are:**
- Indometacin is available in the pack sizes of 28, 56, 84 & 500 Capsules. Not all pack sizes may be marketed.

**Marketing Authorisation Holder Manufacturer:**
**Pharmvit Ltd, 177 Bilton Road, Perivale, Greenford, Middlesex UB6 7HQ.**
**Telephone:** 0208 997 5444
**Fax:** 0208 997 5433

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