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Prescribing Tip For Information

MHRA Alert – Potential risks of prolonged use of Non-Steroidal Anti-inflammatory drugs (NSAID's) after 20 weeks of pregnancy

The MHRA has released a <u>Drug Safety Update</u> following data from a study in 2022 which identified that prolonged use of NSAIDs from week 20 of pregnancy onwards may be associated with an increased risk of oligohydramnios (low levels of amniotic fluid surrounding the baby) and fetal renal dysfunction. Some cases of constriction of the ductus arteriosus (narrowing of a connecting blood vessel in the baby's heart) have also been identified at this early stage. If, following consultation between the patient and a healthcare professional, use of a systemic (oral and injectable) NSAID after week 20 of pregnancy is considered necessary, it should be prescribed for the lowest dose for the shortest time and additional neonatal monitoring considered if used for longer than several days.

The MHRA also want to remind healthcare professionals that use of systemic (oral and injectable) NSAIDs is contraindicated in the last trimester of pregnancy (after 28 weeks of pregnancy). This is due to the increased risks of constriction of the ductus arteriosus and renal dysfunction, which are greater in the last trimester. NSAIDs may also increase maternal bleeding time owing to their anti-platelet-aggregating effect on platelets and may inhibit uterine contractions, resulting in delayed or prolonged labour.

MHRA Information for Healthcare Providers

- A review of data from <u>a 2022 study</u> has identified that prolonged use of NSAIDs from week 20 of pregnancy onwards may be associated with an increased risk of:
 - o oligohydramnios resulting from fetal renal dysfunction; this may occur shortly after initiation, although it is usually reversible upon discontinuation.
 - o cases of constriction of the ductus arteriosus, most of which resolved after treatment cessation.
- Avoid prescribing systemic NSAIDs from week 20 of pregnancy unless clinically required and prescribe the lowest dose for the shortest time.
- Antenatal monitoring for oligohydramnios should be considered if the mother has been exposed to NSAIDs for several days after week 20 of pregnancy; the NSAID should be discontinued if oligohydramnios is found or if the NSAID is no longer considered to be clinically necessary.
- Advise patients who are pregnant to avoid use of NSAIDs available without prescription from week 20 of pregnancy onwards unless advised by their healthcare professional.
- Continue to follow clinical guidelines about taking and recording current and recent medicines, including
 over-the-counter medicines, at each antenatal appointment (for example, see NICE guideline on antenatal care [NG201])
- Report suspected adverse reactions to NSAIDs to the <u>Yellow Card Scheme</u>

The review did not examine topical NSAIDs (gels and creams containing NSAIDs). Healthcare professionals should follow the contraindications and warnings in the <u>product information</u> in relation to pregnancy. Patients who are using gel or creams containing NSAIDs during pregnancy should be advised to read the Patient Information Leaflet for advice.

More information on whether a medicine is safe to use in pregnancy can be found in the following resources:

- Safety in pregnancy SPS Specialist Pharmacy Service The first stop for professional medicines advice
- MHRA Drug Safety Updates
- The Bumps website
- In the products patient information leaflet (PIL) or summary of product characteristics (SPC)