

MHRA

Drug Safety Update

June 2023



Non-steroidal anti-inflammatory drugs (NSAIDs): potential risks following prolonged use after 20 weeks of pregnancy

Advice for healthcare professionals:

- The MHRA reminds healthcare professionals that systemic (oral and injectable) NSAIDs are contraindicated during the last trimester (after 28 weeks) of pregnancy due to the risk of premature closure of the ductus arteriosus and renal dysfunction in the foetus and due to prolongation of maternal bleeding time and inhibition of uterine contractions during labour
- A review of data from a 2022 study has identified that prolonged use of NSAIDs from week 20 of pregnancy onwards may be associated with an increased risk of:
 - oligohydramnios resulting from foetal renal dysfunction; this may occur shortly after initiation, although it is usually reversible upon discontinuation.
 - 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 in these circumstances
- 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 (e.g., see [NICE guideline on antenatal care \[NG201\]](#))
- Report suspected adverse reactions to NSAIDs to the [Yellow Card scheme](#)

Advice for healthcare professionals to provide to patients:

New information for patients about NSAIDs in pregnancy

- NSAID medicines such as ibuprofen, naproxen, and diclofenac are well established medicines for short-term pain relief, but all NSAIDs have recognised side effects and these are listed in the Patient Information Leaflet
- This advice is for oral NSAIDs (taken by mouth) and NSAIDs administered by injection
- If you are pregnant and are worried about taking a NSAID, please discuss this with a healthcare professional who will be able to advise further on your treatment plan
- NSAIDs should not be taken during the third (last) trimester of pregnancy (after 28 weeks of pregnancy) as they can in some cases cause labour to be delayed or last longer than expected. It can also have potential effects on the unborn baby's kidneys and heart
- While it is already well known that NSAIDs should not be taken during the third trimester of pregnancy, new information has identified that there may be potential risks to the baby following prolonged use of a NSAID after week 20 of pregnancy
- This new evidence has shown that prolonged use of NSAIDs after week 20 of pregnancy may increase the risk of problems with the unborn baby's kidneys and heart – however, these effects are usually reversible when the NSAID is stopped
- NSAIDs should be avoided from week 20 of pregnancy onwards unless absolutely necessary and advised by your healthcare professional
- If you and your doctor decide you should take a NSAID during pregnancy, then this should be at the lowest dose for the shortest period
- If you are treated with an NSAID during later pregnancy for more than a few days, your doctor may recommend additional monitoring such as ultrasound scans to check on your baby's health
- It is vitally important that you seek medical advice if pain persists for longer than 3 days or if you have repeated pain during pregnancy