

SINGAPORE, 13 NOVEMBER 2020

HSA UPDATES

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HSA UPDATES NO 10/2020

HSA UPDATES ON RARE KIDNEY PROBLEMS IN UNBORN BABIES WITH THE USE OF NSAIDS IN LATE PREGNANCY

The Health Sciences Authority would like to update that non-steroidal anti-inflammatory drugs (NSAIDs) that are taken around 20 weeks or later in pregnancy may cause rare but serious kidney problems in the unborn baby. Additionally, as the unborn baby's kidneys produce most of the amniotic fluid after approximately 20 weeks of pregnancy, kidney problems can result in low levels of amniotic fluid and pregnancy-related complications.

2 NSAIDs are commonly used for the short-term relief of pain and fever in colds and flu. They include products containing ibuprofen or naproxen which can be bought over the counter, without the need for medical supervision. Please see **Annex A** for the list of oral NSAIDs sold over the counter in Singapore.

3 Currently, the patient information leaflets and package inserts of local products containing NSAIDs already caution against use during pregnancy. HSA will be working with the companies to ensure that the rare potential risk of kidney problems in unborn babies is included in the updated materials. HSA has not received any reports of low levels of amniotic fluid or kidney problems in unborn babies with the use of NSAIDs during pregnancy.

Consumer advisory

- 4 Pregnant women are advised on the following:
- Do not self-medicate with NSAIDs unless advised by your doctor.
 - Consult your healthcare professional if you have questions or concerns about the NSAID medicines you are taking.
 - Check the label on all medicines to see if they are suitable for use during pregnancy before taking them on your own. Consult your healthcare

professional if you are unsure whether these medicines are suitable for you.

5 This safety update follows HSA's assessment of safety information communicated by the United States Food and Drug Administration (FDA) in October 2020¹.

**HEALTH SCIENCES AUTHORITY
SINGAPORE
13 NOVEMBER 2020**

▪ **About the Health Sciences Authority (HSA)**

The Health Sciences Authority (HSA) applies medical, pharmaceutical and scientific expertise through its three professional groups, Health Products Regulation, Blood Services and Applied Sciences, to protect and advance national health and safety. HSA is a multidisciplinary authority. It serves as the national regulator for health products, ensuring they are wisely regulated to meet standards of safety, quality and efficacy. As the national blood service, it is responsible for providing a safe and adequate blood supply. It also applies specialised scientific, forensic, investigative and analytical capabilities in serving the administration of justice. For more details, visit <http://www.hsa.gov.sg/>.

For more updates on public health and safety matters, follow us on Twitter at www.twitter.com/HSASg.

▪ **About HSA Updates**

The "HSA Updates" seeks to provide current information, in a consistent and accurate manner, on topics of public interest. For all issues of HSA Updates, please visit www.hsa.gov.sg, click "Announcements", and select "HSA Updates".

Media representatives are welcome to send any queries to the Corporate Communications Department @ HSA.

¹ <https://www.fda.gov/safety/medical-product-safety-information/nonsteroidal-anti-inflammatory-drugs-nsaids-drug-safety-communication-avoid-use-nsaids-pregnancy-20>

Annex A

Table 1. List of of oral NSAID medicines sold over the counter in Singapore

Name of NSAID	Brand(s) of NSAID medicine
Ibuprofen	Bifen™ Suspension 100mg/5ml Brufen™ Suspension 100mg/5ml Nurofen® Syrup 100mg/5ml Nurofen® Express Liquid Capsules 200mg Nurofen® Express Caplets 342mg Nurofen® Coated Tablets 200mg Nurofen® for Children Suspension 100mg/5ml
Ibuprofen (with paracetamol)	Maxigesic® 150mg/500mg Nuromol™ 200mg/500mg Tablets
Naproxen	Aleve™ Tablets 220mg
Aspirin	Bayer® Aspirin Tablets 500mg Alka-Seltzer™ Effervescent Tablets 324mg Three Legs Medicinal Powder 600mg