

New option for Australians with certain autoimmune diseases through reimbursement of HUMIRA® (adalimumab) citrate-free formulation

Monday 29 March 2021, Sydney – AbbVie (NYSE: ABBV) Australia is pleased to announce that a new formulation of HUMIRA®, known as HUMIRA citrate-free formulation, will be available to eligible Australian patients via the Pharmaceutical Benefits Scheme (PBS) from 1 April 2021.

HUMIRA is currently indicated in Australia for 10 autoimmune conditions across rheumatology, dermatology, gastroenterology and ophthalmology*.¹

Ongoing scientific research and development has enabled the removal of the citrate buffer in the new formulation of HUMIRA. The removal of some inactive ingredients including citrate from HUMIRA, as well as the introduction of a new autoinjector pen and a reduced injection volume (as compared to the previous formulation), is a reflection of AbbVie's commitment taking on board patient feedback.¹

The HUMIRA citrate-free formulation has the same active ingredient (adalimumab), and therefore works in the same way as the previous formulation of HUMIRA.¹ It will be made available for eligible Australian patients, and the previous formulation will eventually be discontinued.

Adam Peacock, Australian sports broadcaster's four-year old daughter, Nylah, lives with Juvenile Idiopathic Arthritis (JIA) and has witnessed firsthand the difficulties his daughter has faced.

"JIA affects our whole family physically, mentally and socially. Seeing your child go through that is heart-wrenching," said Adam. "As a parent with a child who has JIA I am pleased to see that companies continue to invest in existing products."

Leanne Raven, Chief Executive of Crohn's & Colitis Australia, welcomes this new option for Australians living with these complex and often debilitating diseases.

"Chronic autoinflammatory diseases, like Crohn's Disease and ulcerative colitis, can have a significant impact on the quality of life of patients and their families. The long-term nature of these disorders has broader impacts on a person's emotional, physical and social wellbeing," said Ms Raven.

Chris Stemple, General Manager and Vice President of AbbVie Australia, commended the Government's move to reimburse the HUMIRA citrate-free formulation.

"We are proud that AbbVie's continued effort has led to subsidised access to the HUMIRA citrate-free formulation for eligible Australians with autoimmune diseases," said Mr Stemple.

*Ophthalmology indication is not currently listed or reimbursed on the PBS.

“Developing this formulation is part of our ongoing commitment to invest in our medicines to support patients.”

Patients on HUMIRA and their caregivers should consult their healthcare professional with any questions they might have.

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HUMIRA PBS Information: Authority required. Refer to PBS Schedule for full authority information. This product is not listed on the PBS for the treatment of enthesitis-related arthritis, paediatric psoriasis or uveitis. The Humira citrate-free formulation is not currently listed on the PBS.

IMPORTANT INFORMATION ABOUT HUMIRA®²

HUMIRA is a prescription medicine containing adalimumab, an inhibitor of Tumour Necrosis Factor (TNF). HUMIRA is available as a single use, pre-filled syringe or pen in various strengths. It is used in the treatment of patients with rheumatoid arthritis, polyarticular juvenile idiopathic arthritis, enthesitis-related arthritis, psoriatic arthritis, ankylosing spondylitis, Crohn's disease, ulcerative colitis, chronic plaque psoriasis, hidradenitis suppurativa and non-infectious intermediate, posterior or pan-uveitis. HUMIRA is only used in patients of a specific age group (e.g. adult patients only), in diseases of certain severity (e.g. moderate to severe), and/or after some other treatments have been tried (e.g. conventional therapy). Ask your doctor if you have any questions about why HUMIRA may be prescribed for you.

HUMIRA has risks and benefits.

Do not use HUMIRA if you: have an allergy to any medicines containing adalimumab or any of the other ingredients in HUMIRA; have a severe infection including infection of the blood (sepsis), tuberculosis (TB) or any other severe infection; have moderate to severe heart failure; or are using a medicine containing anakinra (Kineret®) or abatacept (Orencia).

Before you use HUMIRA tell your doctor if you have: a current infection or a history of recurring infections (including TB, hepatitis B, fungal or any other infection); any conditions that increase the risk of infections; had close contact with someone with TB; a nervous system disease (such as multiple sclerosis); blood disorders; low resistance to disease; heart conditions; cancer; autoimmune disease; uveitis (an eye problem); lung disease; kidney or liver problems; psoriasis and have undergone phototherapy; or if you have any allergies. Your risk of getting infections or cancer may increase if you take HUMIRA. In rare cases these infections may be life-threatening. Tell your doctor if you are pregnant or plan to become pregnant or if you are breastfeeding or plan to breastfeed. You should consider the use of adequate contraception until at least 5 months after your last HUMIRA treatment. Using HUMIRA during pregnancy is not recommended and it should only be used if clearly needed.

Tell your doctor immediately or go to your nearest hospital if you develop symptoms of: an allergic reaction (such as chest tightness, swelling, rash, shortness of breath or difficulty breathing), heart problems (such as shortness of breath with exertion or upon lying down, swollen feet); or blood disorders (fever, bruising and bleeding easily, paleness);

Tell your doctor right away: if symptoms of TB or any other infection appear during treatment (such as fever, persistent cough, weight loss, feeling tired, skin sores, problems with your teeth or gums, burning when you pass urine, etc); if you develop skin lesions (skin spots or sores) or if existing lesions change appearance; if you develop symptoms of nervous system disorders such as multiple sclerosis (numbness, tingling, muscle weakness, double vision). Tell your doctor right away if you become pregnant while using HUMIRA. If you use HUMIRA during pregnancy, your new born baby may have a higher risk of getting an infection. It is important that you tell your baby's doctors and other healthcare professionals about your HUMIRA use during your pregnancy before the baby receives any vaccine.

Tell your doctor and other healthcare professionals: if you are taking any other medicines, including any that you get without a prescription; if you are going to have surgery, or if you are scheduled for any vaccines. Patients using HUMIRA should not receive any live vaccines. Tell all doctors, dentists, and pharmacists who are treating you that you are using HUMIRA.

Common Side Effects: Tell your doctor if you experience any side effects that make you feel unwell. The more common side effects of HUMIRA are injection site reactions (pain, swelling, redness etc); respiratory tract infections; ear or eye pain, inflammation of the eye or eye lid; headache or migraine; dizziness; tiredness; muscle, joint or bone pain; chest pain; heartburn or reflux; finger or toe nail problems; flushing or increased sweating; burning or pain when passing urine or blood in the urine; hair loss; mouth ulcers; tummy pain; nausea; vomiting; rash; itching; low mood or anxiety; increased heart rate; and infections caused by viruses, bacteria or fungi, etc. HUMIRA may also cause changes that are picked up only through blood tests including reduced blood cell counts, increased liver enzymes and increased lipids.

If you have any questions about using HUMIRA, including the risks and benefits, how much to use, how & when to use it, and appropriate storage conditions, ask your healthcare professional and refer to the Consumer Medicine Information (CMI) available from your pharmacist, by calling AbbVie Pty Ltd on 1800 043 460 or [online at https://moa-api.guildl.ink/documents/vechumixCMI?format=pdf](https://moa-api.guildl.ink/documents/vechumixCMI?format=pdf).

Always use HUMIRA according to your doctor's advice. If symptoms continue, or you have side effects, see your doctor, pharmacist or healthcare professional.

About AbbVie in Australia

AbbVie is a global, research-driven biopharmaceutical company committed to developing innovative advanced therapies for some of the world's most complex and critical conditions. Our heritage in Australia reaches back more than 75 years and we employ more than 320 people with our therapies currently benefiting more than 40,000 Australians. The company's mission is to use its expertise, dedicated people and unique approach to innovation to markedly improve treatments. Recently, we acquired Allergan which immediately diversified our business across several therapeutic areas: Immunology, Hematologic Oncology, Neuroscience and Allergan Aesthetics.

Our commitment to making a remarkable impact doesn't end at developing medicines; it begins there. We provide broader support to our patients and help address the health needs of underserved communities. We strive to protect our environment and to make a positive impact in the areas where we live and work.

For further information please visit www.abbvie.com.au. Follow [@abbvie_AU](https://twitter.com/abbvie_AU) on Twitter, [Facebook](#) or our [LinkedIn](#) page.

References

1. HUMIRA Approved Product Information
2. HUMIRA Consumer Medicines Information.