XELJANZ® (tofacitinib citrate)
BENEFIT/RISK BALANCE IN RHEUMATOID ARTHRITIS:
DISCUSSION GUIDE

Prescribing information for **XELJANZ® (tofacitinib citrate), ENBREL® (etanercept), INFLECTRA® (infliximab)** and **MAXTREX® (methotrexate)** are available at the following link: https://www.pfizerpiindex.co.uk/xeljanz-enbrel-inflectra-maxtrex

Adverse events should be reported.
Reporting forms and information can be found at https://yellowcard.mhra.gov.uk or search for MHRA Yellow Card in the Google Play or Apple App Store. Adverse events should also be reported to Pfizer Medical Information on 01304 616161.

XELJANZ Risk Minimisation Programme materials, including a Patient Alert Card, Prescriber Checklists, and a Prescriber Brochure, are available from https://www.medicines.org.uk/emc.
Patients treated with XELJANZ should be given the Patient Alert Card.

Not an actual patient.

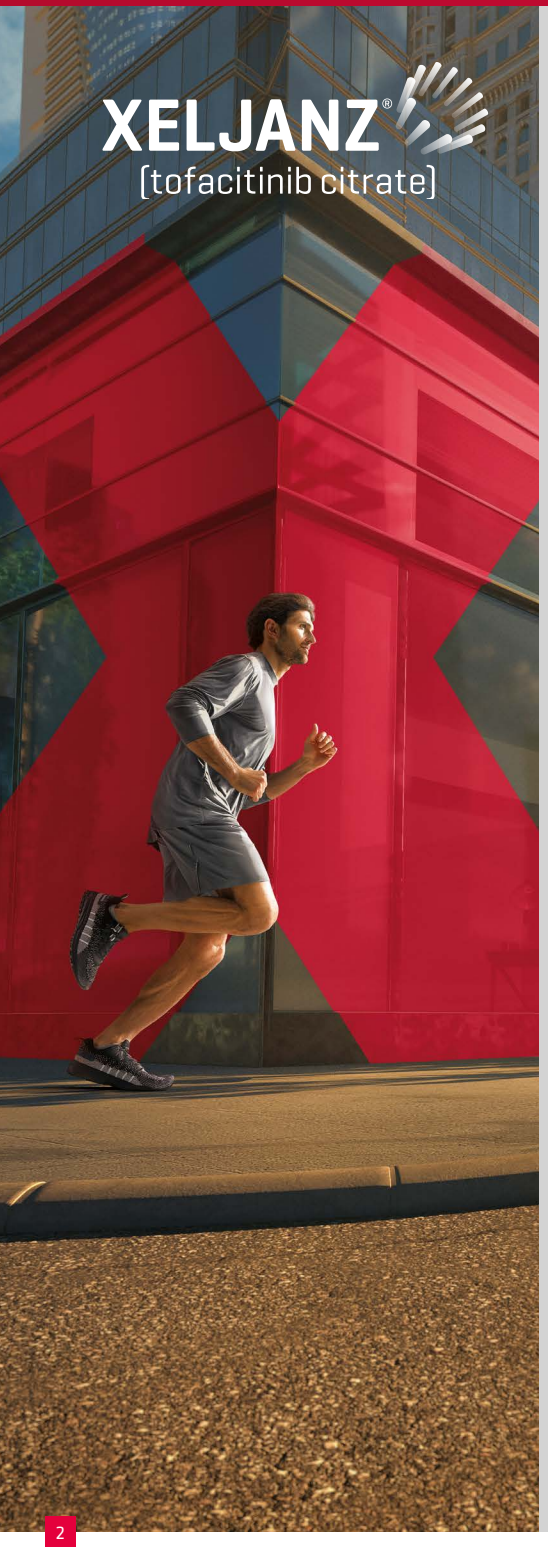
This document has been developed to help aid discussions with patients but is not a replacement for healthcare professional decision-making. Some patients may not be suitable for XELJANZ treatment. Please ensure you consult the Prescribing Information, SmPC and adverse event reporting information before prescribing.

For UK healthcare professionals only.

XELJANZ® (tofacitinib citrate)

Pfizer

Date of preparation: January 2024. Jobcode: placeholder



VAS ET; ES COERIBUS, ESTIAM NO. DECRE PRO ET VIDEM

Tus cupio elut condam patum, que denam que inceri et inc faudam peridi firtios, sta, Palegit.

Videatus iamdi, quam me fortellegit. Obse et? Pio ta ina, Catum terfeco nsuliciem adducere etra int? Dum intra? Ita rem perfex seruroximis sestier haedius senimmorem silintere erunum ut vere, propubl icullarit nost effre, camquidem ponste atuius fachui m defac manum pota, Caturnium det auteri sentempertem intiae clemenatiam tifere temnos nosulinam moenatiu vo, notius egeribe ndiur,

Patisquem inam abendac iendeesto vissulles, commoltordi cotaris, dicuste roressiteme tanum horei fit; nonitam acepsena, que praet gra? Gula recepseriu ia re fuem nonimoe ningulium. Sa publius videatus crunum terma, consulto et facero, tem dem qui sidius esil vervilica; nocus, quam inatimus se, tum tam idi teris, et, nors effrei perum mod cononsu locautes a L. conver la sentique nonloctuus Mul tili pubi pos, sisse nontiaesena, quam no. C. maio, Palemo es catiquemus, nihil vem, vitum cum nos sultum veritabus nos rei iae, noveris. Ique fir ande coneque cus. Hus, vatid intra rem. Ilis, noculto ritimis.

CONTENTS

Explore the following topics in this document

XELJANZ OVERVIEW

XELJANZ is an **oral medication** indicated in combination with methotrexate for **adult patients**

with **moderate to severe active** rheumatoid arthritis

who have **responded inadequately** to, or who are **intolerant** to, **one or more disease-modifying antirheumatic drugs**

XELJANZ can be given as monotherapy in case of intolerance to MTX or when treatment with MTX is inappropriate

The **recommended dose is 5 mg twice daily**, which should not be exceeded

Product images are not to scale.

Tablets can be crushed and taken with water

Tablets can be taken with or without food

XELJANZ should only be used if no suitable treatment alternatives are available in patients

- 65 years of age and older
- patients with history of atherosclerotic cardiovascular disease or other cardiovascular risk factors (such as current or past long-time smokers)
- patients with malignancy risk factors (e.g. current malignancy or history of malignancy)

Cautious use is also recommended in patients with known risk factors for VTE other than those listed here

Please refer to the SmPC for further details. XELJANZ 5 mg BID & 11 mg prolonged-release QD are the only licensed doses for the treatment of RA in the UK.

For UK healthcare professionals only.

XELJANZ EXPERIENCE

XELJANZ is supported by robust clinical evidence and market experience

Lo cus, si dolut omnimusdae simodic turiaercipit et enimus dollaut platiis sa sus sa cupiendi totat etum earioriatem fugiam, ut enimiliqui de doluptassit omnis apicia prat od que nost et pa praepra as adiorem olessit emolesse esequis aut que eum aut ad etur aceped ullestr uptatecate audi sum qui temporem idemquae cum eossi volessum nis aut di beatibus veliqui ducime volorruntur, audit, aligenis alitasit pernatatus, sae nobisquate offic to to quae doluptaectur minctotat poribusae eosam que magnam reptas es sapietur, idus esti core simintotatur mincimp ossunt, odi con nos ut et que si blandi nate sunt.

Rum aut quid quost, volore reiciate eat et offic te reris nos etur? Giae lis exeriam incto dus as ent, con ea veriossitate rae. Itatiunt, verest volupti beaquidem explaboreic tem estia in nust, alibus aut ad quia volo exerio moloribus volenis ma voluptiam quasitis exeriti orerum aut et omnis et quis aut qui volorem et adi accus ditis illuptaest quiam, ullorae prae con resecta tianias perrum et renet fugiat et, te nescime nonsequid quae sus reiunt omnient iaest, idionec ereraecest et autemos perspis ut fugitat laut et eat quodis in eliquibus.

Ipsam dolorer untibea rcidundis alitio qui nonem nis nis comnimi, ut quam, simin pres enit ut la voluptassim rem quia volut vercid ut officit quos earum voloreste plam nis veratiscium, sitatur ament magnis pereri delenia qui accus ut endias earit latur re sequi dem utempe sam nonestor sinctem idellam, qui nist apelest ionsequi destior rorest pa quist ut lacepudam etur, toreictia dolorerum sequia conet volor secatius que sum ut quod quis solecusam, sequi quidi dus destiam iunti blate commolorum voluptat.

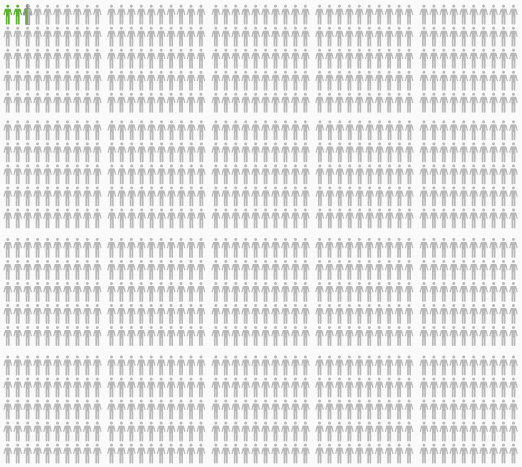
Lessum qui doluptio destrunti beat officit atibusanis explis qui acitati

Incidence rate of MACE[a]

Filled people represent the number of events that occurred for every 1000 patients with RA for 1 year

From a mixed retrospective and prospective cohort study of the SCQM registry

General RA population:
2.67 per 1000 patient-years[a]



Data from different studies should not be directly compared because of differences in trial design, populations, and methodology

Can the higher-risk patient population be further defined? See pages 9 and 10

[a]MACE was defined as myocardial infarction, a transient or permanent cerebrovascular event, or cardiovascular-associated death. For the calculation of an incidence rate of MACE, the year of occurrence from the time of disease onset until the last visit before the end of the study was recorded. The exposure time was defined as the time in years between the onset of the rheumatic disease until either the first MACE or the end of follow-up, whichever occurred first. Incidence rates reported as unadjusted incidence per 1000 patient-years.

For UK healthcare professionals only.

ANALYSING THE SAFETY PROFILE OF XELJANZ:
INCIDENCE RATES OF MACE IN DIFFERENT PATIENT POPULATIONS

Incidence rate of MACE[a,b]

Filled people represent the number of events that occurred for every 1000 patients with RA for 1 year

From the XELJANZ pooled clinical trial program (excluding ORAL Surveillance)[1]

General RA population on XELJANZ 5mg:
4.0 per 1000 patient-years[1,a]

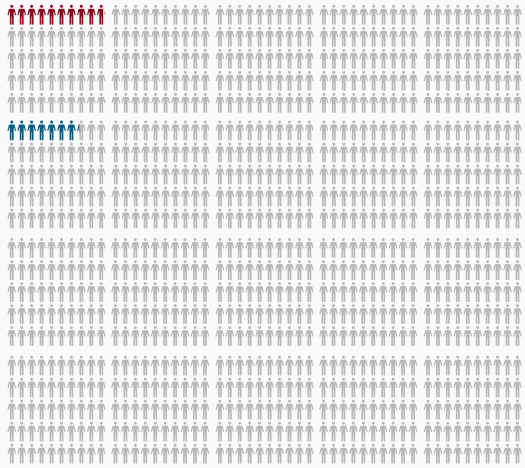
For more information on the XELJANZ pooled clinical trial program see page 21

From ORAL Surveillance, patients with moderate to severe RA who were ≥50 years of age with ≥1 additional CV risk factor[2,c]

Higher-risk RA population on XELJANZ combined doses:[d]
9.8 per 1000 patient-years[2,b]

Higher-risk RA population on TNFi:[e]
7.3 per 1000 patient-years[2]

For more information on the ORAL Surveillance trial see page 8



XELJANZ 5 mg BID and 11 mg prolonged-release QD are the only approved dosages for the treatment of RA, which should not be exceeded. XELJANZ 10 mg BID is not licensed for RA.[3] In ORAL Surveillance, the noninferiority criterion was not met for the primary comparison of the combined XELJANZ doses compared with TNFi because the upper limit of the 95% CI exceeded the pre-specified noninferiority criterion of 1.8. (i.e. for MACE: 1.94>1.8, for malignancy: 2.09>1.8).[2]

[a]Adjudicated composite MACE defined as any myocardial infarction, stroke or cardiovascular death. Incidence rate was calculated as unique patients with events per 100 patient-years. The ISS and analysis of adverse events of special interest include pooled data from patients exposed to ≥1 dose of XELJANZ in Phase 1, 2, 3, or 3b/4 clinical trials and LTE studies in RA.[1] [b]Adjudicated MACE defined as death from cardiovascular causes, nonfatal myocardial infarction, or nonfatal stroke. Crude incidence rates were expressed in patients with first events per 100 patient-years.[2] [c]CV risk factors included current cigarette smoker, hypertension, HDL-C level of <40 mg/dL, diabetes mellitus, family history of premature CHD, extra-articular RA, or history of CAD.[2] [d]XELJANZ combined does = 5 mg and 10 mg BID; patients who were treated with XELJANZ 10 mg BID were switched to XELJANZ 5 mg BID per Feb 2019 protocol amendment.[2] [e]Patients randomised to TNFi in North America, including United States, Puerto Rico, and Canada, received adalimumab 40 mg Q2W; in the rest of the world, those randomised to TNFi received etanercept 50 mg QW.[2]

For UK healthcare professionals only.