Xeljanz - (5 mg; Tablet, Oral)

Generic Name	Tofacitinib	**Innovator**	Pfizer
Dosage	5 mg; Tablet, Oral	**Branded US Sales**	Less Than $1000 mn
Probable FTF	Less Than 5	**Known Para IV Filers**	More Than 5
Other ANDA developers	More Than 5	**Tentative Approvals**	More Than 5
Final Approvals	More Than 5	**Generic Launches**	More Than 5
Indication	Used to treat moderate to severe rheumatoid arthritis or active psoriatic arthritis (PsA) in adults who have tried methotrexate other medications without successful treatment of symptoms		
Complexities	Yes		

Chronology Of Events

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Executive Summary

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Chronology Of Events

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Xeljanz - (10 mg; Tablet, Oral)

Generic Name	Tofacitinib	**Innovator**	Pfizer
Dosage	10 mg; Tablet, Oral	**Branded US Sales**	Less Than $1000 mn
Probable FTF	Less Than 5	**Known Para IV Filers**	More Than 5
Other ANDA developers	More Than 5	**Tentative Approvals**	Less Than 5
Final Approvals	More Than 5	**Generic Launches**	More Than 5
Indication	Xeljanz is indicated for the treatment of adult patients with active psoriatic arthritis (PsA) who have had an inadequate response or intolerance to methotrexate or other disease-modifying antirheumatic drugs.		
Complexities	Yes		

Chronology Of Events

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Xeljanz - (1 mg/mL ; Oral Solution)

Generic Name	Tofacitinib	**Innovator**	Pfizer
Dosage	1 mg/mL ; Oral Solution	**Branded US Sales**	Less Than $1000 mn
Probable FTF	Less Than 5	**Known Para IV Filers**	Less Than 5
Other ANDA developers	Less Than 5	**Tentative Approvals**	Less Than 5
Final Approvals	Less Than 5	**Generic Launches**	Less Than 5
Indication	XELJANZ/XELJANZ XR/XELJANZ Oral Solution is a Janus kinase (JAK) inhibitor indicated for: 1) Rheumatoid Arthritis - XELJANZ/XELJANZ XR is indicated for the treatment of adult patients with moderately to severely active rheumatoid arthritis who have had an inadequate response or intolerance to methotrexate. 2) Psoriatic Arthritis - XELJANZ/XELJANZ XR is indicated for the treatment of adult patients with active psoriatic arthritis who have had an inadequate response or intolerance to methotrexate or other disease-modifying antirheumatic drugs (DMARDs). ? Limitations of Use: Use of XELJANZ/XELJANZ XR in combination with biologic DMARDs or potent immunosuppressants such as azathioprine and cyclosporine is not recommended. 3) Ulcerative Colitis - XELJANZ/XELJANZ XR is indicated for the treatment of adult patients with moderately to severely active ulcerative colitis (UC), who have had an inadequate response or who are intolerant to TNF blockers. 4) Polyarticular Course Juvenile Idiopathic Arthritis - XELJANZ/XELJANZ Oral Solution is indicated for the treatment of active polyarticular course juvenile idiopathic arthritis (pcJIA) in patients 2 years of age and older.		
Complexities	Yes		

Chronology Of Events

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