



MAPI PROLabels Summary Report

DRUG NAME	THERAPEUTIC AREA	THERAPEUTIC INDICATION	PRO ENDPOINT IN THE LABEL	PRO ENDPOINT NOT IN THE LABEL
Aerius	Immune System diseases Otorhinolaryngologic Diseases Respiratory Tract Diseases	Rhinitis-Allergic, perennial and seasonal	2-week average change from baseline of the subject' total reflective symptom scores	Quality of life using the 8 SF-36 scales and the 2-component summary scores of the SF-36
Allegra	Immune System diseases Otorhinolaryngologic Diseases Respiratory Tract Diseases	Rhinitis-Allergic, seasonal	Change from baseline in the average instantaneous total symptom scores (TSS)	Change from baseline in the average 24-hour reflective TSS; average 12 hour reflective TSS for both morning and evening; average individual instantaneous symptoms score
Allegra-D 24 hour	Immune System diseases Otorhinolaryngologic Diseases Respiratory Tract Diseases	Rhinitis-Allergic, seasonal	Change from baseline in the average instantaneous total symptom scores (TSS)	Change from baseline in the average 24-hour reflective TSS; average 12 hour reflective TSS for both morning and evening; average individual 24- hour reflective symptoms score; average individual instantaneous symptoms score
Amitiza	Pathological conditions-signs and conditions	Constipation-Chronic idiopathic constipation	Assessments for abdominal bloating and discomfort, constipation severity, and treatment effectiveness	Quality of life assessed using SF-36
Arava	Musculoskeletal diseases, Skin and Connective Tissue Diseases	Psoriatic arthritis	Superior efficacy compared to placebo in subjects with psoriatic arthritis by means of Psoriatic Arthritis Treatment Response Criteria (PsARC) at 24 weeks	Quality of life objectives-Mean Health Assessment Questionnaire (HAQ) scores, MOS SF-36, and Dermatology Life Quality Index (DLQI)
Arava	Immune System Diseases, Musculoskeletal diseases, Skin and Connective Tissue Diseases	Rheumatoid Arthritis	Percentage of ACR20 responder at endpoint. ACR20 responder-A patient who met the 20% improvement condition	The Problem Elicitation Technique (PET) Questionnaire – a preference disability questionnaire

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Ariclaim	Pathological conditions-Signs and Symptoms	Diabetic Peripheral Neuropathic Pain in adults	Weekly mean of 24-hour average pain	Response rates, Brief Pain Inventory (BPI)-Severity and Interference, the Patient's Global Impressions of Improvement (PGI Improvement), the sensory portion of the Short-Form McGill Pain Questionnaire (SF-MPQ), the Beck Depression Inventory-II (BDI-II), the Beck Anxiety Inventory (BAI), the HAMD17, the SF-36, and EQ-5D
Celebrex	Immune System Diseases, Musculoskeletal diseases, Skin and Connective Tissue Diseases	Rheumatoid Arthritis	ACR20 responder index	Patient's assessment of pain (VAS), the SF-36 Health Survey, the duration of morning stiffness, the HAQ Functional Disability Index, and the ACR50 responder Index
Circadin	Mental Disorders Nervous System Diseases	Sleep initiation, and maintenance disorders	Quality of sleep, and morning alertness, rate of responders in the Circadin vs. Placebo groups, sleep latency, quality of life	Remaining derived parameters from the LSEQ (GTS and AES) and the sleep diary parameters QON (Quality of Night) and QOD (Quality of Day) and the SF-36
Clarinx	Immune System diseases Otorhinolaryngologic Diseases Respiratory Tract Diseases	Rhinitis-Allergic, seasonal	Change from baseline in average reflective 12-hour AM/PM TSS over 2 week of treatment	Overall condition assessed by the patient, and evaluation of the therapeutic response by the patient, QOL assessment using the SF-36 Health Survey, and the Rhinoconjunctivitis QOL Questionnaire (RQLQ)
Cymbalta	Endocrine System Diseases Nervous System Diseases	Diabetic Peripheral Neuropathic Pain in adults	Weekly mean of 24-hour average pain (Primary endpoint), response rate and clinical response rate (secondary endpoint)	Brief Pain Inventory (BPI)-Severity and Interference, the Patient's Global Impressions of Improvement (PGI Improvement), the sensory portion of the Short-Form McGill Pain Questionnaire (SF-MPQ), Dynamic allodynia, the Beck Depression Inventory-II (BDI-II), the Beck Anxiety Inventory (BAI), the SF-36, and EQ-5D

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Cymbalta	Endocrine System Diseases Nervous System Diseases	Diabetic Peripheral Neuropathic Pain	Change from baseline in the weekly mean of 24-hour average pain measure	Response and sustained response rates, weekly means of night and worst daily pain from the daily diary, Brief Pain Inventory (BPI)-Severity and Interference, the Patient's Global Impressions of Improvement (PGI Improvement, the Beck Depression Inventory-II (BDI-II), the Beck Anxiety Inventory (BAI), the SF-36, and EQ-5D
Enbrel	Immune System Diseases, Musculoskeletal diseases, Skin and Connective Tissue Diseases	Rheumatoid Arthritis	ACR-N response criteria	QOL assessment using SF-36
Enbrel	Musculoskeletal diseases, Skin and Connective Tissue Diseases	Psoriatic Arthritis	Improvement in 3 months as assessed by ACR20, ACR20 at 6 months, and mean change in the baseline from SF-36	Psoriatic arthritis response criteria (PsARC) at 2 and 6 months
Fabrazyme	Congenital, Hereditary, and Neonatal Diseases and Abnormalities Nervous System Diseases Nutritional and Metabolic Diseases	Fabry disease	Reduction in pain assessed by the Short Form McGill Pain Questionnaire, and QOL	No additional PRO endpoint
Humira	Musculoskeletal diseases, Skin and Connective Tissue Diseases	Psoriatic Arthritis	ACR20 response at week 12	Secondary endpoints related to PsARC, PASI, Quality of life assessments which also included Functional Assessment of Chronic Illness Therapy (FACIT) Fatigue Scale Score, and the Dermatology Life Quality Index (DLQI)
Humira	Musculoskeletal diseases, Skin and Connective Tissue Diseases	Psoriatic Arthritis	ACR20 response at week 12 and week 24	Not reported
Kentera	Male Urogenital Diseases	Urinary Incontinence	Change in the average number of urinary incontinence episodes per day from baseline	Comparisons of daily urinary frequency, urinary volume per void, QOL scores, Patient Global Assessment of Disease State. QOL was assessed using SF-36, Incontinence Impact Questionnaire (IIQ),

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				Urogenital Distress Inventory (UDI)
Kineret	Immune System Diseases, Musculoskeletal diseases, Skin and Connective Tissue Diseases	Rheumatoid Arthritis	ACR20 response at 6 months. Secondary endpoints-ACR50 and ACR70 response at 6 months, and means change in the ACR components	Mean change in the duration of morning sickness, proportion of subjects who experienced a sustained ACR20 response
Lotronex	Digestive System Diseases	Irritable Bowel Syndrome	Proportion of days with urgency, adequate relief of IBS pain/discomfort, proportion of pain/discomfort free days, lower GI functions, psychological distress evaluation, QOL measures using Irritable Bowel Syndrome QOL questionnaire and SF-36	Not reported
Lyrica	Nervous system diseases Pathological conditions-signs and symptoms Psychological phenomena and processes	Peripheral and central neuropathic pain in adults	Weekly mean pain score at endpoint	Short-Form McGill Pain Questionnaire (SFMPQ), sleep interference scale, global impression of change by patient (PGIC), SF-36 QOL questionnaire, Hospital anxiety and depression scale, European QOL questionnaire, Medical Outcome Sleep Scale
Mabthera	Immune System Diseases, Musculoskeletal diseases, Skin and Connective Tissue Diseases	Rheumatoid Arthritis	Percent of patients who achieved an ACR20 response at week 24, Disease activity score	Not reported
Mirapexin	Mental disorders Nervous system disorders	Restless Legs Syndrome	Mean change in baseline from the Restless Legs Syndrome Rating Scale (IRLS), and Clinical Global Impression Improvement (CGI-I)	QOL assessment using Johns Hopkins RLS QOL scale and SF-36, sleep using the Epworth Sleepiness Scale (ESS), RLS severity using a VAS and Patient Global Impression (PGI)

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Neoclarityn	Immune System diseases Otorhinolaryngologic Diseases Respiratory Tract Diseases	Rhinitis-Allergic-Perennial and Seasonal	2-week average change from baseline of the subject's total reflective symptom score, secondary endpoint-QOL	QOL evaluated using the 8 SF-36 scales and the two-component summary scores of the SF-36
Orencia	Immune System Diseases, Musculoskeletal diseases, Skin and Connective Tissue Diseases	Rheumatoid Arthritis	ACR response at 6 months. Secondary endpoints-Change in functional status and health-related QOL	Not reported
Orencia	Immune System Diseases, Musculoskeletal diseases, Skin and Connective Tissue Diseases	Rheumatoid Arthritis	ACR20. Secondary endpoint-Improvement in physical function, Health-related QOL	DAS28 score
Osseor	Musculoskeletal Diseases	Postmenopausal Osteoporosis	Quality of life	Not reported
PegIntron	Digestive System Diseases Virus Diseases	Chronic Hepatitis C	Health-related quality of life	Not reported
Pletal	Cardiovascular Diseases	Intermittent claudication	QOL assessment using the Walking	QOL using SF-36, Claudication Outcome Measure (COM), physical activity recall (PAR) questionnaire, Sickness Impact Profile (SIP)
Protelos	Musculoskeletal diseases	Postmenopausal osteoporosis	Quality of life	Not reported
Provigil	Mental disorders Nervous system diseases	Disorders of excessive somnolence	Epworth Sleepiness Scale, change from baseline on the ESS at week 4 or final visit	Patient's daily sleep log, QOL in Narcolepsy (QOLIN) scale
Remicade	Musculoskeletal diseases, Skin and Connective Tissue Diseases	Psoriatic arthritis	ACR20. Secondary endpoints-percentage ACR20 overtime, ACR50, ACR70, and QOL	Not reported
Remicade	Musculoskeletal diseases, Skin and Connective Tissue Diseases	Psoriatic arthritis	ACR 20 % response at week 54, HAQ disability index (HAQ-DI), SF-36 health survey	Not reported
Replagal	- Congenital, Hereditary, and Neonatal Diseases and Abnormalities - Nervous System Diseases - Nutritional and Metabolic Diseases	Fabry disease	Effect of the enzyme replacement on serious debilitating pain, as measured by the brief pain inventory (BPI)	QOL assessment using SF-36 health survey

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Sifrol	Mental disorders Nervous system diseases	Restless Legs Syndrome	Mean change in baseline from the Restless Legs Syndrome Rating Scale (IRLS), and Clinical Global Impression Improvement (CGI-I)	QOL assessment using Johns Hopkins RLS QOL scale and SF-36, sleep using the Epworth Sleepiness Scale (ESS), RLS severity using a VAS and Patient Global Impression (PGI)
Somavert	- Endocrine System Diseases - Musculoskeletal Diseases - Nervous System Diseases	Acromegaly	Change in the signs and symptoms of acromegaly scores-secondary endpoint	Changes in QOL assessed using SF-36 mental component score and physical component score, and the brain tumor module of the functional assessment of cancer therapy (FACT-Br) total score
Spiriva	Respiratory tract diseases	Chronic Obstructive Pulmonary Disease (COPD)	Use of rescue medication-secondary endpoint	Weekly mean PEFR measured by the patient at home twice daily, number of nocturnal awakenings during the first 13 weeks, and two health-related QOL assessment, the disease-specific Saint George's Respiratory Questionnaire (SGRQ), SF-36
Thyrogen	Diagnosis	Thyroid function tests	Quality of life-secondary endpoint	Profile of Moods States in the diagnosis states
Thyrogen	Diagnosis	Thyroid function tests	Quality of life-secondary endpoint	Not reported
Trudexa	Musculoskeletal diseases, Skin and Connective Tissue Diseases	Psoriatic arthritis	ACR 20 response at week 12	Secondary endpoints relating to Psoriatic Arthritis Response Criteria (PsARC), PASI and QOL assessments using the Functional Assessment of Chronic Illness Therapy (FACIT) Fatigue Scale Score, and Dermatology Life Quality Index (DLQI)
Ultram ER	Opioids	- Musculoskeletal Diseases - Nervous System Diseases - Pathological Conditions, Signs and Symptoms - Psychological Phenomena and Processes	Change from baseline measured at 1,2,3,6,9 and 12 weeks by the WOMAC pain subscale	WOMAC function subscale, the Patient Global Assessment of Disease Activity, report of pain intensity in daily diaries, WOMAC OA Index pain subscale, arthritis pain intensity VAS score in the index joint and non-index joint, SF-36 health survey component summary and Chronic Pain Sleep Inventory (CPSI) scales during overall quality of sleep

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ViraferonPeg	Digestive system diseases Virus diseases	Hepatitis C	Health-related Quality of life	Not reported
Xeristar	Endocrine system diseases Nervous system diseases	Diabetic peripheral neuropathic pain in adults	Weekly mean of 24 hour average pain. Secondary endpoints- Response rate and clinical response rate	Brief Pain Inventory (BPI) Severity and Interference, the Patient's Global Impressions of Improvement (PGI Improvement), sensory portion of the Short-Form McGill Pain Questionnaire (SF-MPQ), Dynamic Allodynia, The Beck Depression Inventory-II (BDI-II), the Beck Anxiety Inventory (BAI), and Health Outcome Measures using SF-36 and EQ-5D