



Mass General Brigham

JAK Inhibitors for Alopecia Areta: Practical Pearls from Over a Decade of Use

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Director, Atopic Dermatitis Program
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Professor, Harvard Medical School

Disclosures

- Disclosures:
 - Consultant and/or Principal Investigator: Apogee, Abbvie, AstraZeneca, BMS, Priovant, Johnson & Johnson, Lilly
- Therapies reviewed in this presentation involve off-label use of medications



The Dermatology Foundation has supported and advanced my career



Case 1





**Failed: prednisone, HCQ, MTX,
mycophenolate mofetil, lenalidomide,
dapsons, IVIG**





Tofacitinib 10mg BID





Tofacitinib 10mg BID



Tofacitinib Citrate for Refractory Cutaneous Dermatomyositis: An Alternative Treatment

JAMA Dermatology

April 27, 2016

A Before treatment



B After treatment



- Mean decrease in CDASI: 12
- Decreased pruritus

Kurtzman D and Vleugels RA





Tofacitinib 5 mg BID

The NEW ENGLAND JOURNAL of MEDICINE

ESTABLISHED IN 1812

AUGUST 9, 2012

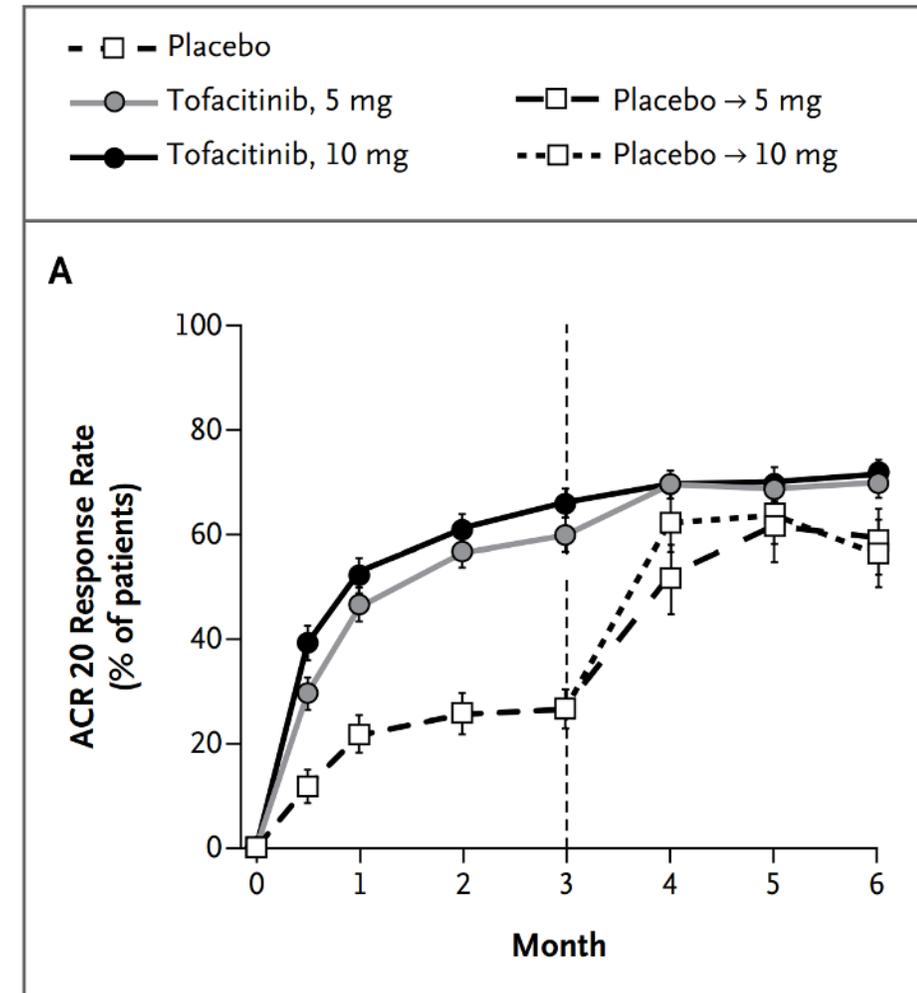
VOL. 367 NO. 6

Placebo-Controlled Trial of Tofacitinib Monotherapy in Rheumatoid Arthritis

Roy Fleischmann, M.D., Joel Kremer, M.D., John Cush, M.D., Hendrik Schulze-Koops, M.D., Ph.D., Carol A. Connell, Ph.D., John D. Bradley, M.D., David Gruben, Ph.D., Gene V. Wallenstein, Ph.D., Samuel H. Zwillich, M.D., and Keith S. Kanik, M.D., for the ORAL Solo Investigators*

- **At month 3 – at least 20% improvement in ACR20**
 - **Placebo: 26.7%**
 - **5 mg BID: 59.8%**
 - **10 mg BID: 65.7%**

ACR 20 = American College of Rheumatology scale.
Fleischmann R, et al. *N Engl J Med.* 2012;367(6):495-507.



FDA Approval Timeline

Tofacitinib – RA

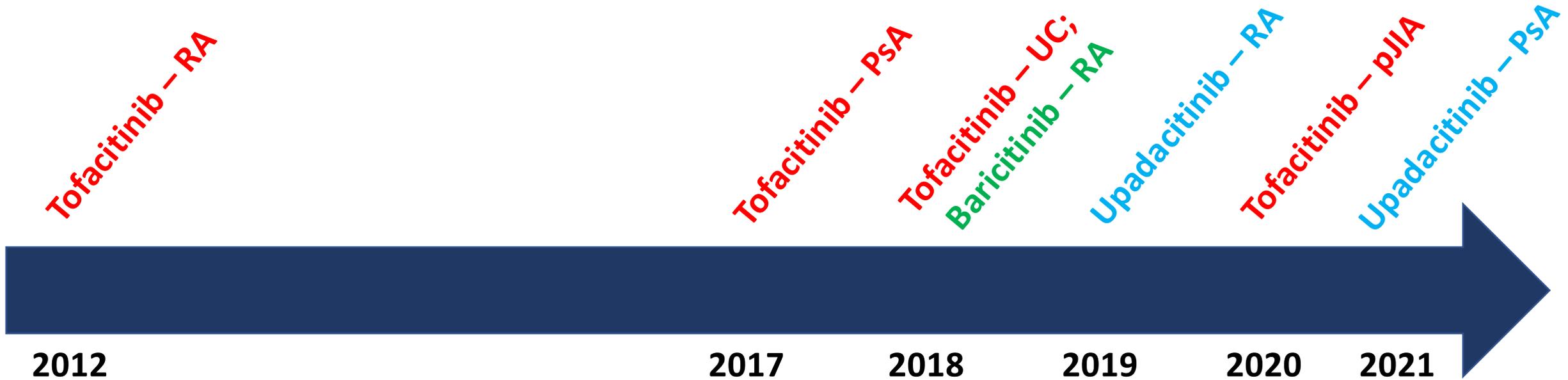


2012

RA = rheumatoid arthritis

US Food and Drug Administration. Drugs@FDA: FDA-Approved Drugs. Accessed August 2, 2021. www.accessdata.fda.gov/scripts/cder/daf/.

FDA Approval Timeline



Case 2





Tofacitinib
10 mg BID







Tofacitinib 5 mg BID

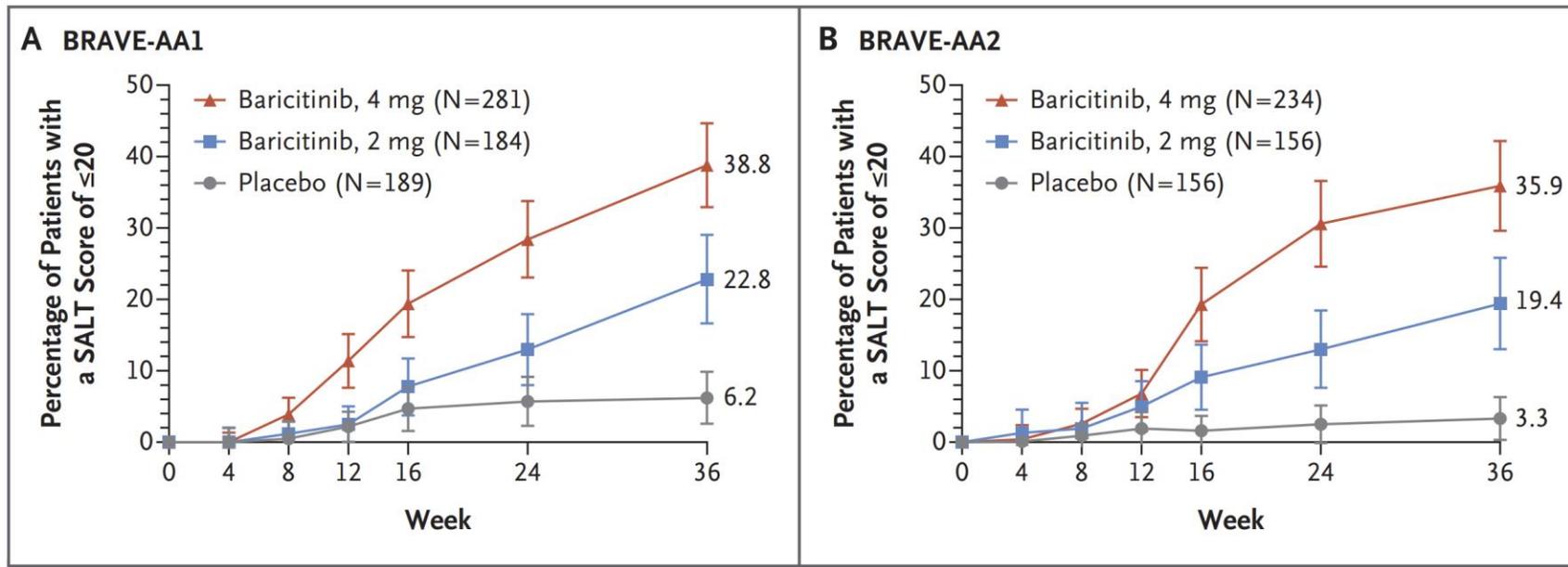


Tofacitinib 5 mg BID

ORIGINAL ARTICLE

Two Phase 3 Trials of Baricitinib for Alopecia Areata

Brett King, M.D., Ph.D., Manabu Ohya, M.D., Ph.D.,
 Ohsang Kwon, M.D., Ph.D., Abraham Zlotogorski, M.D., Justin Ko, M.D.,
 Natasha A. Mesinkovska, M.D., Ph.D., Maria Hordinsky, M.D.,
 Yves Dutronc, M.D., Wen-Shuo Wu, M.D., Jill McCollam, Pharm.D.,
 Chiara Chiasserini, Sc.D., Guanglei Yu, Ph.D., Sarah Stanley, Ph.D.,
 Katrin Holzwarth, M.D., Amy M. DeLozier, M.P.H., and Rodney Sinclair, M.D.,
 for the BRAVE-AA Investigators*







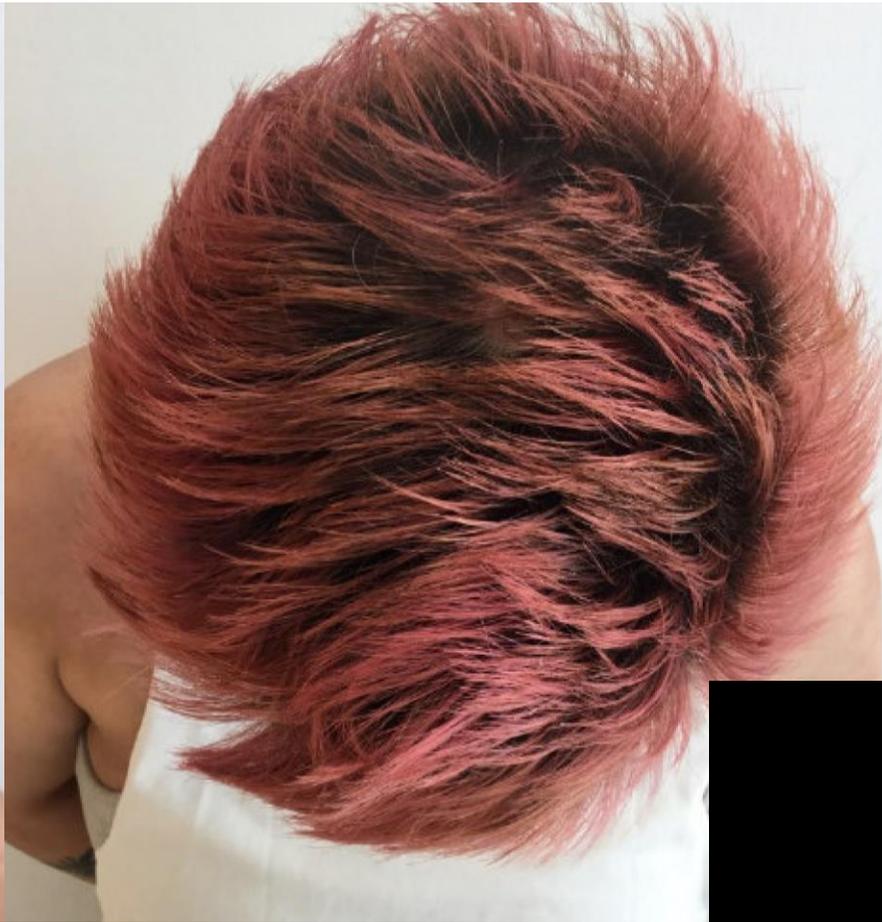
Baricitinib 2mg QD

Baricitinib 2mg QD









Clinical Pearls over a Decade: JAK Inhibitors

- Many skin diseases warrant higher dose
 - Children reach adult doses by 40kg, often sooner

Clinical Pearls over a Decade: JAK Inhibitors

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- Safe to combine with MTX
 - Pre-JAK inhibitors, MTX was a “go-to” systemic for AA

Clinical Pearls over a Decade: JAK Inhibitors

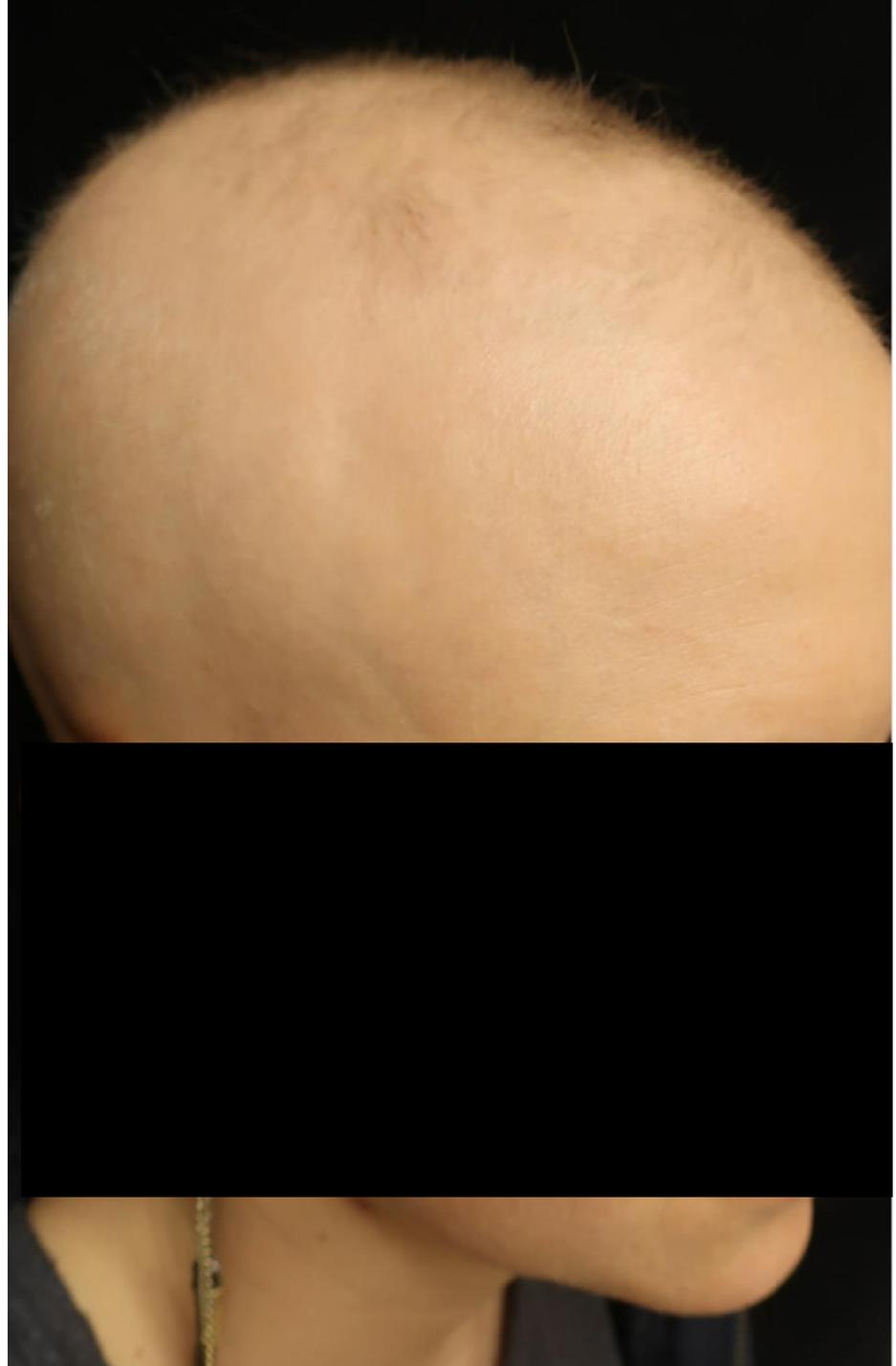
- Many skin diseases warrant higher dose
 - Children reach adult doses by 40kg, often sooner
- Rapid onset of action
- Safe to combine with MTX
 - Pre-JAK inhibitors, MTX was a “go-to” systemic for AA
- Shingrix – killed shingles vaccine (now recommended by CDC in anyone 18+ who will be immunosuppressed)

Clinical Pearls over a Decade: JAK Inhibitors

- Many skin diseases warrant higher dose
 - Children reach adult doses by 40kg, often sooner
- Rapid onset of action
- Safe to combine with MTX
 - Pre-JAK inhibitors, MTX was a “go-to” systemic for AA
- Shingrix – killed shingles vaccine (now recommended by CDC in anyone 18+ who will be immunosuppressed)
- Extremely well-tolerated day-to-day

Case 3





How do I counsel about a boxed warning?

BOXED WARNING

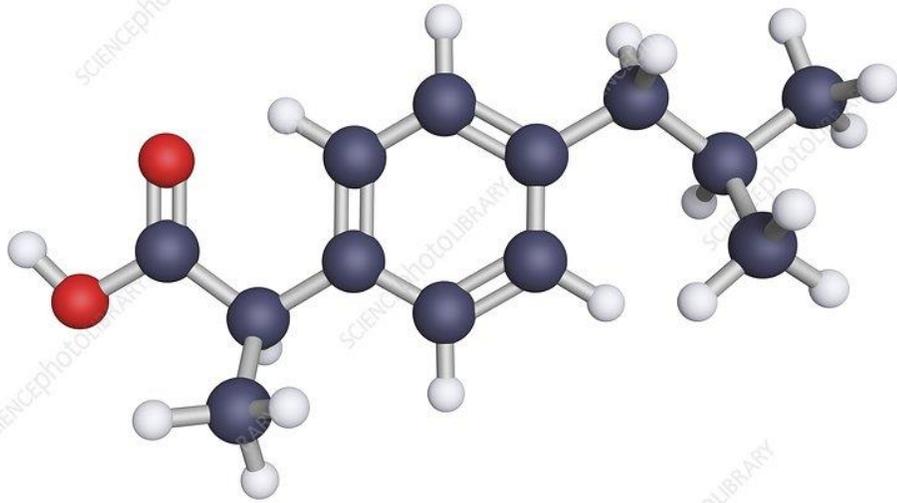
Cardiovascular Thrombotic Events

1. Nonsteroidal anti-inflammatory drugs (NSAIDs) cause an increased risk of serious cardiovascular thrombotic events, including myocardial infarction and stroke, which can be fatal. This risk may occur early in treatment and may increase with duration of use. (See [WARNINGS](#) and [PRECAUTIONS](#)).
1. IBU tablets are contraindicated in the setting of coronary artery bypass graft (CABG) surgery (See [CONTRAINDICATIONS](#) and [WARNINGS](#)).

Gastrointestinal Risk

1. NSAIDs cause an increased risk of serious gastrointestinal adverse events including bleeding, ulceration, and perforation of the stomach or intestines, which can be fatal. These events can occur at any time during use and without warning symptoms. Elderly patients are at greater risk for serious gastrointestinal events. (See [WARNINGS](#)).

[CLOSE](#)



> 50 drugs used in dermatology have a boxed warning

Drugs Used in Dermatology With Boxed Warnings ^{16*}		
Drug Name	Brand	Summary of boxed warning
Methotrexate	Trexall®	Appropriate use, fetal death/congenital abnormalities, impaired drug elimination, concomitant NSAID use warning, hepatotoxicity, pulmonary toxicity, gastrointestinal toxicity, malignant lymphoma, tumor lysis syndrome, skin reactions, opportunistic infections, concomitant radiotherapy risks
Methoxsalen (8-methoxypsoralen)	Oxsoralen Ultra®, 8-MOP®, Oxsoralen lotion®	Appropriate use by experienced physicians, ocular/skin damage, skin cancer, non-interchangeable forms with other methoxsalen products
Moxifloxacin	Avelox®	Risk of tendon rupture and tendonitis, avoid in myasthenia gravis
Mycophenolate mofetil	CellCept®	Appropriate use by experienced physicians, risks in pregnancy, immunosuppressant
Norgestimate/ethinyl estradiol	Ortho Tri-Cyclen®, Ortho Tri-Cyclen Lo®	Smoking and cardiovascular events
Norelgestromin; ethinyl estradiol	Ortho Evra®	Smoking and cardiovascular events, venous thromboembolism risk, ethinyl estradiol pharmacokinetic profile
Norfloxacin	Noroxin®	Risk of tendon rupture and tendonitis, avoid in myasthenia gravis
Ofloxacin	Floxin®	Risk of tendon rupture and tendonitis, avoid in myasthenia gravis
Pegylated IFN-alfa 2a	Pegasys®	Fatal/life-threatening events, warning with concomitant ribavirin
Pegylated IFN-alfa 2b	PEG-Intron®	Fatal/life-threatening events, warning with concomitant ribavirin
Pimecrolimus topical	Elidel®	Rare malignancies
Pimozide	Orap®	Dementia-related psychosis
Rituximab	Rituxan®	Fatal infusion reactions, tumor lysis syndrome, severe mucocutaneous reactions, progressive multifocal leukoencephalopathy
Sirolimus	Rapamune®	Appropriate use, immunosuppressant, use not recommended in liver and lung transplantation
Spironolactone	Aldactone®	Tumor risk
Tacrolimus topical	Protopic®	Rare malignancies
Thalidomide	Thalomid®	Restricted use through Thalomid REMS, embryo-fetal toxicity, venous thromboembolic events

Drugs Used in Dermatology With Boxed Warnings ^{16*}		
Drug Name	Brand	Summary of boxed warning
AbobotulinumtoxinA	Dysport®	Potential life-threatening distant spread of toxin effect after local injection
Acitretin	Soriatane®	Pregnancy and blood donation contraindicated; appropriate use by experienced physicians, considerations in women of child-bearing potential, alcohol avoidance, hepatotoxicity
Adalimumab	Humira®	Serious infection risk, malignancy risk
Azathioprine	Imuran®, Azasan®	Malignancy risk, mutagenic potential in males and females, hematologic toxicity
Bexarotene	Targretin®	Pregnancy contraindicated
OnabotulinumtoxinA	Botox®, Botox Cosmetic®	Potential life-threatening distant spread of toxin effect after local injection
Isotretinoin	Accutane®	Restricted use through iPLEDGE, pregnancy contraindicated
Intravenous immunoglobulin (IVIg)	Gammalex®, Gammagard®, Gamunex®, Carimune NF®, Privigen®, Flebogamma®	Acute renal dysfunction/failure
Certolizumab Pegol	Cimzia®	Serious infection risk, malignancy
Ciprofloxacin	Cipro®, Cipro XR®	Risk of tendon rupture and tendonitis, avoid in myasthenia gravis
Chlorambucil	Leukeran®	Myelosuppression, carcinogen, mutagen/teratogen, infertility
Chloroquine phosphate	Aralen®	Appropriate use for malaria and extraintestinal amebiasis
Clindamycin	Cleocin®	<i>C. difficile</i> associated diarrhea risk
Cyclosporine modified	Neoral®	Appropriate use in experienced physicians, immunosuppressant, bioequivalence, monitor drug levels, skin malignancy risk in psoriasis, hypertension and nephrotoxicity risks
Doxepin	Silenor®	Suicidality risk in children, adolescents, young adults
Drospirenone/ethinyl estradiol	Gianvi®, Loryna®, Ocella®, Syeda®, Vestura®, Zarah®, Yaz®, Yazmin®, Beyaz®	Smoking and cardiovascular events
Etanercept	Enbrel®	Serious infection risk, malignancy
Gemifloxacin	Factive®	Risk of tendon rupture and tendonitis, avoid in myasthenia gravis
Golimumab	Simponi®	Serious infection risk, malignancy
Hydroxychloroquine	Plaquenil®	Prescribers should be familiar with complete prescribing information
Infliximab	Remicade®	Serious infection risk, malignancy
Interferon alfa 2b	Intron A®	Fatal/life-threatening events
Itraconazole	Sporanox®, Onmel®	Contraindicated in ventricular dysfunction (CHF, CHF history) patients, potent CYP3A4 inhibitor
Ketoconazole	Nizoral®	Hepatotoxicity risk, potent CYP3A4 inhibitor
Levofloxacin	Levaquin®	Risk of tendon rupture and tendonitis, avoid in myasthenia gravis

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Antimicrobials

Drugs Used in Dermatology With Boxed Warnings ^{16*}		
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Methotrexate	Trexall®	Appropriate use, fetal death/congenital abnormalities, impaired drug elimination, concomitant NSAID use warning, hepatotoxicity, pulmonary toxicity, gastrointestinal toxicity, malignant lymphoma, tumor lysis syndrome, skin reactions, opportunistic infections, concomitant radiotherapy/radiation
Methoxsalen (8-methoxypsoralen)	Oxsoralen Ultra®, 8-MOP®, Oxsoralen lotion®	Appropriate use by experienced physicians, ocular/skin damage, skin cancer, non-interchangeable forms with other methoxsalen products
Moxifloxacin	Avelox®	Risk of tendon rupture and tendonitis, avoid in myasthenia gravis
Mycophenolate mofetil	CellCept®	Appropriate use by experienced physicians, risks in pregnancy, immunosuppressant
Norgestimate/ethinyl estradiol	Ortho Tri-Cyclen®, Ortho Tri-Cyclen Lo®	Smoking and cardiovascular events
Norelgestromin; ethinyl estradiol	Ortho Evra®	Smoking and cardiovascular events, venous thromboembolism risk, ethinyl estradiol pharmacokinetic profile
Norfloxacin	Noroxin®	Risk of tendon rupture and tendonitis, avoid in myasthenia gravis
Ofloxacin	Floxin®	Risk of tendon rupture and tendonitis, avoid in myasthenia gravis
Pegylated IFN-alfa 2a	Pegasys®	Fatal/life-threatening events, warning with concomitant ribavirin
Pegylated IFN-alfa 2b	PEG-Intron®	Fatal/life-threatening events, warning with concomitant ribavirin
Pimecrolimus topical	Elidel®	Rare malignancies
Pimozide	Orap®	Dementia-related psychosis
Rituximab	Rituxan®	Fatal infusion reactions, tumor lysis syndrome, severe mucocutaneous reactions, progressive multifocal leukoencephalopathy
Sirolimus	Rapamune®	Appropriate use, immunosuppressant, use not recommended in liver and lung transplantation
Spironolactone	Aldactone®	Tumor risk
Tacrolimus topical	Protopic®	Rare malignancies
Thalidomide	Thalomid®	Restricted use through Thalomid REMS, embryo-fetal toxicity, venous thromboembolic events

Drugs Used in Dermatology With Boxed Warnings ^{16*}		
Drug Name	Brand	Summary of boxed warning
AbobotulinumtoxinA	Dysport®	Potential life-threatening distant spread of toxin effect after local injection
Acitretin	Soriatane®	Pregnancy and blood donation contraindicated; appropriate use by experienced physicians, considerations in women of child-bearing potential, alcohol avoidance, hepatotoxicity
Adalimumab	Humira®	Serious infection risk, malignancy risk
Adalimumab	Imuran®, Azasan®	Malignancy risk, mutagenic potential in males and females, hematologic toxicity
Bexarotene	Targretin®	Pregnancy contraindicated
OnabotulinumtoxinA	Botox®, Botox Cosmetic®	Potential life-threatening distant spread of toxin effect after local injection
Isotretinoin	Accutane®	Restricted use through iPLEDGE, pregnancy contraindicated
Intravenous immunoglobulin (IVIg)	Gammalex®, Gammagard®, Gamunex®, Carimune NF®, Privigen®, Flebogamma®	Acute renal dysfunction/failure
Certolizumab Pegol	Cimzia®	Serious infection risk, malignancy
Ciprofloxacin	Cipro®, Cipro XR®	Risk of tendon rupture and tendonitis, avoid in myasthenia gravis
Chlorambucil	Leukeran®	Myelosuppression, carcinogen, mutagen/teratogen, infertility
Chloroquine phosphate	Aralen®	Appropriate use for malaria and extraintestinal amebiasis
Clindamycin	Cleocin®	<i>C. difficile</i> associated diarrhea risk
Cyclosporine modified	Neoral®	Appropriate use in experienced physicians, immunosuppressant, bioequivalence, monitor drug levels, skin malignancy risk in psoriasis, hypertension and nephrotoxicity risks
Doxepin	Silenor®	Suicidality risk in children, adolescents, young adults
Drospirenone/ethinyl estradiol	Gianvi®, Loryna®, Ocella®, Syeda®, Vestura®, Zarah®, Yaz®, Yazmin®, Beyaz®	Smoking and cardiovascular events
Etanercept	Enbrel®	Serious infection risk, malignancy
Gemifloxacin	Factive®	Risk of tendon rupture and tendonitis, avoid in myasthenia gravis
Golimumab	Simponi®	Serious infection risk, malignancy
Hydroxychloroquine	Plaquenil®	Prescribers should be familiar with complete prescribing information
Infliximab	Remicade®	Serious infection risk, malignancy
Interferon alfa 2b	Intron A®	Fatal/life-threatening events
Itraconazole	Sporanox®, Onmel®	Contraindicated in ventricular dysfunction (CHF, CHF history) patients, potent CYP3A4 inhibitor
Ketoconazole	Nizoral®	Hepatotoxicity risk, potent CYP3A4 inhibitor
Levofloxacin	Levaquin®	Risk of tendon rupture and tendonitis, avoid in myasthenia gravis

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Methoxsalen (8-methoxypsoralen)	Oxsoralen Ultra®, 8-MOP®, Oxsoralen lotion®	Appropriate use by experienced physicians, ocular/skin damage, skin cancer, non-interchangeable forms with other methoxsalen products
Moxifloxacin	Avelox®	Risk of tendon rupture and tendonitis, avoid in myasthenia gravis
Mycophenolate mofetil	CellCept®	Appropriate use by experienced physicians, risks in pregnancy, immunosuppressant
Norgestimate/ethinyl estradiol	Ortho Tri-Cyclen®, Ortho Tri-Cyclen Lo®	Smoking and cardiovascular events
Norelgestromin; ethinyl estradiol	Ortho Evra®	Smoking and cardiovascular events, venous thromboembolism risk, ethinyl estradiol pharmacokinetic properties
Norfloxacin	Noroxin®	Risk of tendon rupture and tendonitis, avoid in myasthenia gravis
Ofloxacin	Floxin®	Risk of tendon rupture and tendonitis, avoid in myasthenia gravis
Pegylated IFN-alfa 2a	Pegasys®	Fatal/life-threatening events, warning with concomitant zalcitabine
Pegylated IFN-alfa 2b	PEG-Intron®	Fatal/life-threatening events, warning with concomitant zalcitabine
Pimecrolimus topical	Elidel®	Rare malignancies
Pimozide	Orap®	Dementia-related psychosis
Rituximab	Rituxan®	Fatal infusion reactions, tumor lysis syndrome, severe mucocutaneous reactions, progressive multifocal leukoencephalopathy
Sirolimus	Rapamune®	Appropriate use, immunosuppressant, use not recommended in liver and lung transplantation
Spironolactone	Aldactone®	Tumor risk
Tacrolimus topical	Protopic®	Rare malignancies
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Adalimumab	Humira®	Serious infection risk, malignancy risk
Azathioprine	Imuran®, Azasan®	Malignancy risk, mutagenic potential in males and females, hematologic toxicity
Bexarotene	Targretin®	Pregnancy contraindicated
OnabotulinumtoxinA	Botox®, Botox Cosmetic®	Potential life-threatening distant spread of toxin effect after local injection
Isotretinoin	Accutane®	Restricted use through iPLEDGE, pregnancy contraindicated
Intravenous immunoglobulin (IVIg)	Gammalex®, Gammagard®, Gamunex®, Carimune NF®, Priviligen®, Flebogamma®	Acute renal dysfunction/failure
Certolizumab Pegol	Cimzia®	Serious infection risk, malignancy
Ciprofloxacin	Cipro®, Cipro XR®	Risk of tendon rupture and tendonitis, avoid in myasthenia gravis
Chlorambucil	Leukeran®	Myelosuppression, carcinogen, mutagen/teratogen, infertility
Chloroquine phosphate	Aralen®	Appropriate use for malaria and extraintestinal amebiasis
Cloxacillin	Cleocin®	<i>C. difficile</i> associated diarrhea risk
Cyclosporine modified	Neoral®	Appropriate use in experienced physicians, immunosuppressant, bioequivalence, monitor drug levels, skin malignancy risk in psoriasis, hypertension and nephrotoxicity risks
Doxepin	Silenor®	Suicidality risk in children, adolescents, young adults
Drospirenone/ethinyl estradiol	Gianvi®, Loryna®, Ocella®, Syeda®, Vestura®, Zarah®, Yaz®, Yazmin®, Beyaz®	Smoking and cardiovascular events
Etanercept	Enbrel®	Serious infection risk, malignancy
Gemifloxacin	Factive®	Risk of tendon rupture and tendonitis, avoid in myasthenia gravis
Golimumab	Simponi®	Serious infection risk, malignancy
Hydroxychloroquine	Plaquenil®	Prescribers should be familiar with complete prescribing information
Infliximab	Remicade®	Serious infection risk, malignancy
Interferon alfa 2b	Intron A®	Fatal/life-threatening events
Itraconazole	Sporanox®, Onmel®	Contraindicated in ventricular dysfunction (CHF, CHF history) patients, potent CYP3A4 inhibitor
Ketoconazole	Nizoral®	Hepatotoxicity risk, potent CYP3A4 inhibitor
Levofloxacin	Levaquin®	Risk of tendon rupture and tendonitis, avoid in myasthenia gravis

Isotretinoin Retinoids

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Methoxsalen (8-methoxypsoralen)	Oxsoralen Ultra®, 8-MOP®, Oxsoralen lotion®	Appropriate use by experienced physicians, ocular/skin damage, skin cancer, non-interchangeable forms with other methoxsalen products
Moxifloxacin	Avelox®	Risk of tendon rupture and tendonitis, avoid in myasthenia gravis
Mycophenolate mofetil	CellCept®	Appropriate use by experienced physicians, risks in pregnancy, immunosuppressant
Norgestimate/ethinyl estradiol	Ortho Tri-Cyclen®, Ortho Tri-Cyclen Lo®	Smoking and cardiovascular events
Norelgestromin; ethinyl estradiol	Ortho Evra®	Smoking and cardiovascular events, venous thromboembolism, risk of myasthenia gravis, pharmacokinetic interactions
Norfloxacin	Noroxin®	Risk of tendon rupture and tendonitis, avoid in myasthenia gravis
Ofloxacin	Floxin®	Risk of tendon rupture and tendonitis, avoid in myasthenia gravis
Pegylated IFN-alfa 2a	Pegasys®	Fatal/life-threatening events, warning with concomitant ribavirin
Pegylated IFN-alfa 2b	PEG-Intron®	Fatal/life-threatening events, warning with concomitant ribavirin
Pimecrolimus topical	Elidel®	Rare malignancies
Pimozide	Orap®	Dementia-related psychosis
Rituximab	Rituxan®	Fatal infusion reactions, tumor lysis syndrome, severe mucocutaneous reactions, progressive multifocal leukoencephalopathy
Sirolimus	Rapamune®	Appropriate use, immunosuppressant, use not recommended in liver and lung transplantation
Spironolactone	Aldactone®	Tumor risk
Tacrolimus topical	Protopic®	Rare malignancies
Thalidomide	Thalomid®	Restricted use through Thalomid REMS, embryo-fetal toxicity, venous thromboembolic events

Botulinum Toxins

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Ciprofloxacin	Cipro®, Cipro XR®	Risk of tendon rupture and tendonitis, avoid in myasthenia gravis
Chlorambucil	Leukeran®	Myelosuppression, carcinogen, mutagen/teratogen, infertility
Chloroquine phosphate	Palfer®	Appropriate use for malaria and extraintestinal amebiasis
Clindamycin	Cleocin®	<i>C. difficile</i> associated diarrhea risk
Cyclosporine modified	Neoral®	Appropriate use in experienced physicians, immunosuppressant, bioequivalence, monitor drug levels, skin malignancy risk in psoriasis, hypertension and nephrotoxicity risks
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Gemifloxacin	Factive®	Risk of tendon rupture and tendonitis, avoid in myasthenia gravis
Golimumab	Simponi®	Serious infection risk, malignancy
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Pimecrolimus topical	Elidel®	Appropriate use in children and adolescents, avoid in patients with active or recent bacterial, viral, or fungal infections
Pimozide	Orapron®	Appropriate use in children and adolescents, avoid in patients with active or recent bacterial, viral, or fungal infections
Rituximab	Humira®	Appropriate use in experienced physicians, immunosuppressant, bioequivalence, monitor drug levels, skin malignancy risk in psoriasis, hypertension and nephrotoxicity risks
Sirolimus	Rapamune®	Appropriate use, immunosuppressant, use not recommended in liver and lung transplantation
Spirolactone	Aldactone®	Tumor risk
Tacrolimus topical	Protopic®	Rare malignancies
Thalidomide	Thalomid®	Restricted use through Thalomid REMS, embryo-fetal toxicity, venous thromboembolic events

Drugs Used in Dermatology With Boxed Warnings ^{16*}		
Drug Name	Brand	Summary of boxed warning
AbobotulinumtoxinA	Dysport®	Potential life-threatening distant spread of toxin effect after local injection
Acitretin	Soriatane®	Pregnancy and blood donation contraindicated; appropriate use by experienced physicians, considerations in women of child-bearing potential, alcohol avoidance, hepatotoxicity
Adalimumab	Humira®	Serious infection risk, malignancy risk
Azathioprine	Imuran®, Azasan®	Malignancy risk, mutagenic potential in males and females, hematologic toxicity
Bexarotene	Targretin®	Pregnancy contraindicated
OnabotulinumtoxinA	Botox®, Botox Cosmetic®	Potential life-threatening distant spread of toxin effect after local injection
Isotretinoin	Accutane®	Restricted use through iPLEDGE, pregnancy contraindicated
Intravenous immunoglobulin (IVIg)	Gammalex®, Gammagard®, Gamunex®, Carimune NF®, Priviligen®, Flebogamma®	Acute renal dysfunction/failure
Certolizumab Pegol	Cimzia®	Serious infection risk, malignancy
Ciprofloxacin	Cipro®, Cipro XR®	Risk of tendon rupture and tendonitis, avoid in myasthenia gravis
Chlorambucil	Leukeran®	Myelosuppression, carcinogen, mutagen/teratogen, infertility
Chloroquine phosphate	Aralen®	Appropriate use for malaria and extraintestinal amebiasis
Clindamycin	Cleocin®	<i>C. difficile</i> associated diarrhea risk
Cyclosporine modified	Neoral®	Appropriate use in experienced physicians, immunosuppressant, bioequivalence, monitor drug levels, skin malignancy risk in psoriasis, hypertension and nephrotoxicity risks
Doxepin	Silenor®	Suicidality risk in children, adolescents, young adults
Drospirenone/ethinyl estradiol	Gianvi®, Loryna®, Ocella®, Syeda®, Vesio®, Zayza®, Yaz®, Yazmin®, Beyaz®	Smoking and cardiovascular events
Erythromycin	Ery-Tab®, Ery-Tab®	Serious infection risk, malignancy
Geacifloxacin	Proxive®	Risk of tendon rupture and tendonitis, avoid in myasthenia gravis
Golimumab	Simponi®	Serious infection risk, malignancy
Hydroxychloroquine	Plaquenil®	Prescribers should be familiar with complete prescribing information
Infliximab	Remicade®	Serious infection risk, malignancy
Interferon alfa 2b	Intron A®	Fatal/life-threatening events
Itraconazole	Sporanox®, Onmel®	Contraindicated in ventricular dysfunction (CHF, CHF history) patients, potent CYP3A4 inhibitor
Ketoconazole	Nizoral®	Hepatotoxicity risk, potent CYP3A4 inhibitor
Levofloxacin	Levaquin®	Risk of tendon rupture and tendonitis, avoid in myasthenia gravis

Immunosuppressives

> 50 drugs used in dermatology have a boxed warning

Drugs Used in Dermatology With Boxed Warnings ^{16*}		
Drug Name	Brand	Summary of boxed warning
Methotrexate	Trexall®	Appropriate use, fetal death/congenital abnormalities, impaired drug elimination, concomitant NSAID use warning, hepatotoxicity, pulmonary toxicity, gastrointestinal toxicity, malignant lymphoma, tumor lysis syndrome, skin reactions, opportunistic infections, concomitant radiotherapy risks
Methoxsalen (8-methoxypsoralen)	Oxsoralen Ultra®, 8-MOP®, Oxsoralen lotion®	Appropriate use by experienced physicians, ocular/skin damage, skin cancer, non-interchangeable forms with other methoxsalen products
Moxifloxacin	Avelox®	Risk of tendon rupture and tendonitis, avoid in myasthenia gravis
Mycophenolate mofetil	CellCept®	Appropriate use by experienced physicians, risks in pregnancy, immunosuppressant
Norgestimate/ethinyl estradiol	Ortho Tri-Cyclen®, Ortho Tri-Cyclen Lo®	Smoking and cardiovascular events
Norelgestromin; ethinyl estradiol	Ortho Evra®	Smoking and cardiovascular events, venous thromboembolism risk, ethinyl estradiol pharmacokinetic profile
Norfloxacin	Noroxin®	Risk of tendon rupture and tendonitis, avoid in myasthenia gravis
Ofloxacin	Floxin®	Risk of tendon rupture and tendonitis, avoid in myasthenia gravis
Pegylated IFN-alfa 2a	Pegasys®	Fatal/life-threatening events, warning with concomitant ribavirin
Pegylated IFN-alfa 2b	PEG-Intron®	Fatal/life-threatening events, warning with concomitant ribavirin
Pimecrolimus topical	Elidel®	Rare malignancies
Pimozide	Orap®	Dementia-related psychosis
Rituximab	Rituxan®	Fatal infusion reactions, tumor lysis syndrome, severe mucocutaneous reactions, progressive multifocal leukoencephalopathy
Sirolimus	Rapamune®	Appropriate use, immunosuppressant, use not recommended in liver and lung transplantation
Spironolactone	Aldactone®	Tumor risk
Tacrolimus topical	Protopic®	Rare malignancies
Thalidomide	Thalomid®	Restricted use through Thalomid REMS, embryo-fetal toxicity, venous thromboembolic events

TNF-α Inhibitors

Drugs Used in Dermatology With Boxed Warnings ^{16*}		
Drug Name	Brand	Summary of boxed warning
AbobotulinumtoxinA	Dysport®	Potential life-threatening distant spread of toxin effect after local injection
Acitretin	Soriatane®	Pregnancy and blood donation contraindicated; appropriate use by experienced physicians, considerations in women of child-bearing potential, alcohol avoidance, hepatotoxicity
Adalimumab	Humira®	Serious infection risk, malignancy risk
Azathioprine	Imuran®, Azasan®	Malignancy risk, mutagenic potential in males and females, hematologic toxicity
Bexarotene	Targretin®	Pregnancy contraindicated
OnabotulinumtoxinA	Botox®, Botox Cosmetic®	Potential life-threatening distant spread of toxin effect after local injection
Isotretinoin	Accutane®	Restricted use through iPLEDGE, pregnancy contraindicated
Intravenous immunoglobulin (IVIg)	Gammalex®, Gammagard®, Gamunex®, Carimune NF®, Privigen®, Flebogamma®	Acute renal dysfunction/failure
Certolizumab Pegol	Cimzia®	Serious infection risk, malignancy
Ciprofloxacin	Cipro®, Cipro XR®	Risk of tendon rupture and tendonitis, avoid in myasthenia gravis
Chlorambucil	Leukeran®	Myelosuppression, carcinogen, mutagen/teratogen, infertility
Chloroquine phosphate	Aralen®	Appropriate use for malaria and extraintestinal amebiasis
Clarithromycin	Cleocin®	<i>C. difficile</i> associated diarrhea risk
Cyclosporine modified	Neoral®	Appropriate use in experienced physicians, immunosuppressant, bioequivalence, monitor drug levels, skin malignancy risk in psoriasis, hypertension and nephrotoxicity risks
Doxepin	Silenor®	Suicidality risk in children, adolescents, young adults
Drospirenone/ethinyl estradiol	Gianvi®, Loryna®, Ocella®, Syeda®, Vestura®, Zarah®, Yaz®, Yazmin®, Beyaz®	Smoking and cardiovascular events
Etanercept	Enbrel®	Serious infection risk, malignancy
Gemifloxacin	Factive®	Risk of tendon rupture and tendonitis, avoid in myasthenia gravis
Golimumab	Simponi®	Serious infection risk, malignancy
Hydroxychloroquine	Plaquenil®	Prescribers should be familiar with complete prescribing information
Infliximab	Remicade®	Serious infection risk, malignancy
Interferon alfa 2b	Intron A®	Fatal/life-threatening events
Itraconazole	Sporanox®, Onmel®	Contraindicated in ventricular dysfunction (CHF, CHF history) patients, potent CYP3A4 inhibitor
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Immunomodulatory

JAK inhibitors: Appropriate Patient Selection

- Start with explaining JAKis approved ~13 years – for AA/AD, the indication may be new, but **not** the medicine

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 - Clot hx?
 - Heart attack or stroke?
 - Active malignancy? Cancer history/up to date on screening?

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 - Heart attack or stroke?
 - Active malignancy? Cancer history/up to date on screening?
- Signal for zoster
- Follow: CBC with diff, LFTs, renal function, lipids





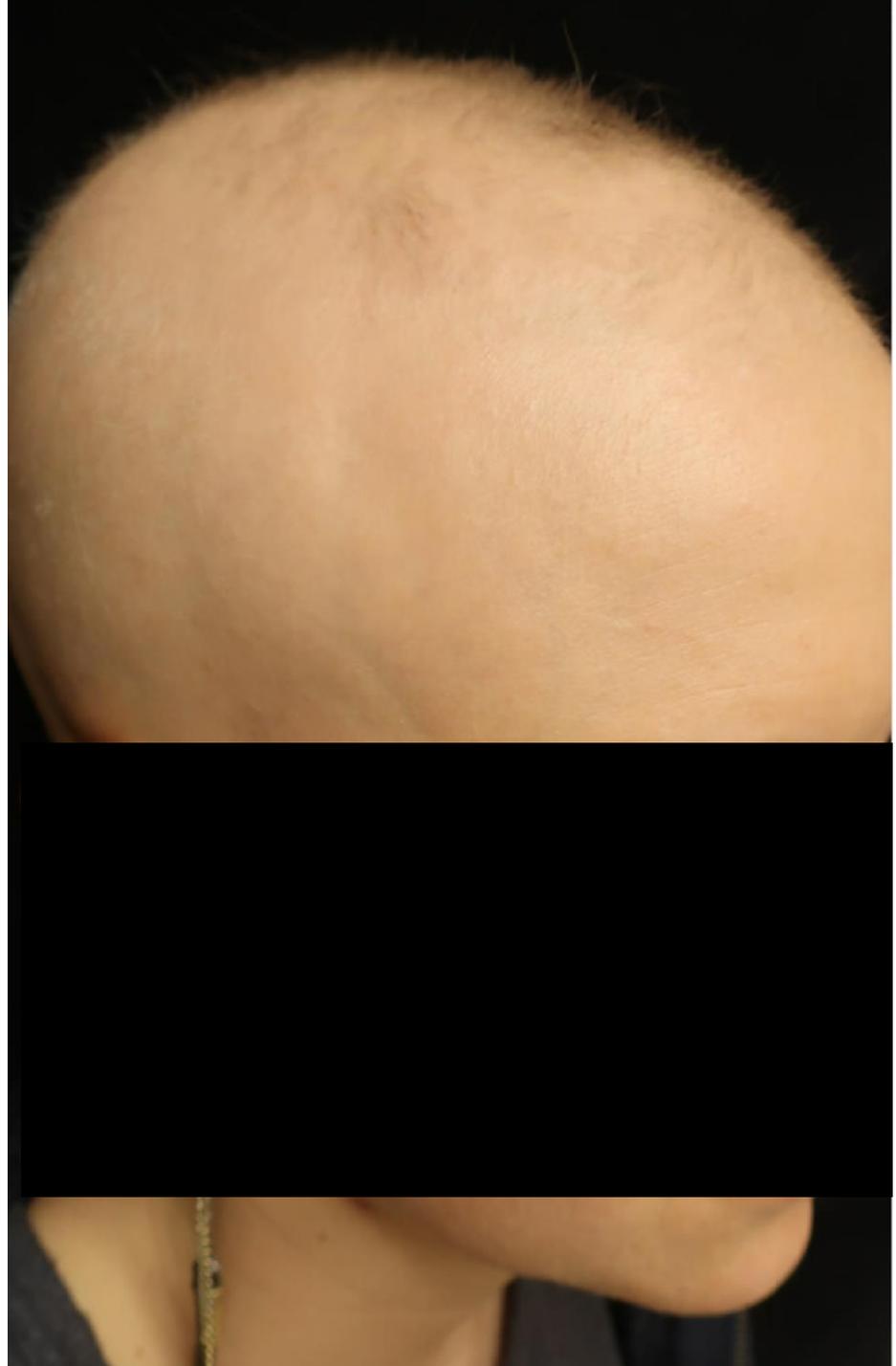
- Man in his 40s; also has mild inflammatory bowel disease
- Risk related to VTE, MACE, cancer
 - Clot hx? **NO**
 - Heart attack or stroke? **NO**
 - Active malignancy? Cancer history/up to date on screening?
NO cancer history and up to date

**Baricitinib 4mg QD
3 months**



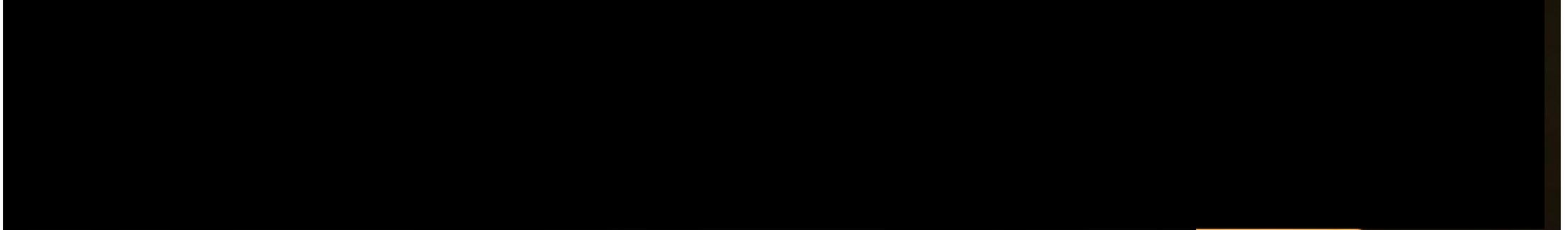
Baricitinib 4mg QD
1 year







- Woman in her 30s
- Risk related to VTE, MACE, cancer
 - Clot hx? **NO**
 - Heart attack or stroke? **NO**
 - Active malignancy? Cancer history/up to date on screening?
NO cancer history and up to date





- Man in his late 40s
- Risk related to VTE, MACE, cancer
 - Clot hx? **NO**
 - Heart attack or stroke? **NO, but does have hyperlipidemia and HTN**
 - Active malignancy? Cancer history/up to date on screening?
NO cancer history and up to date



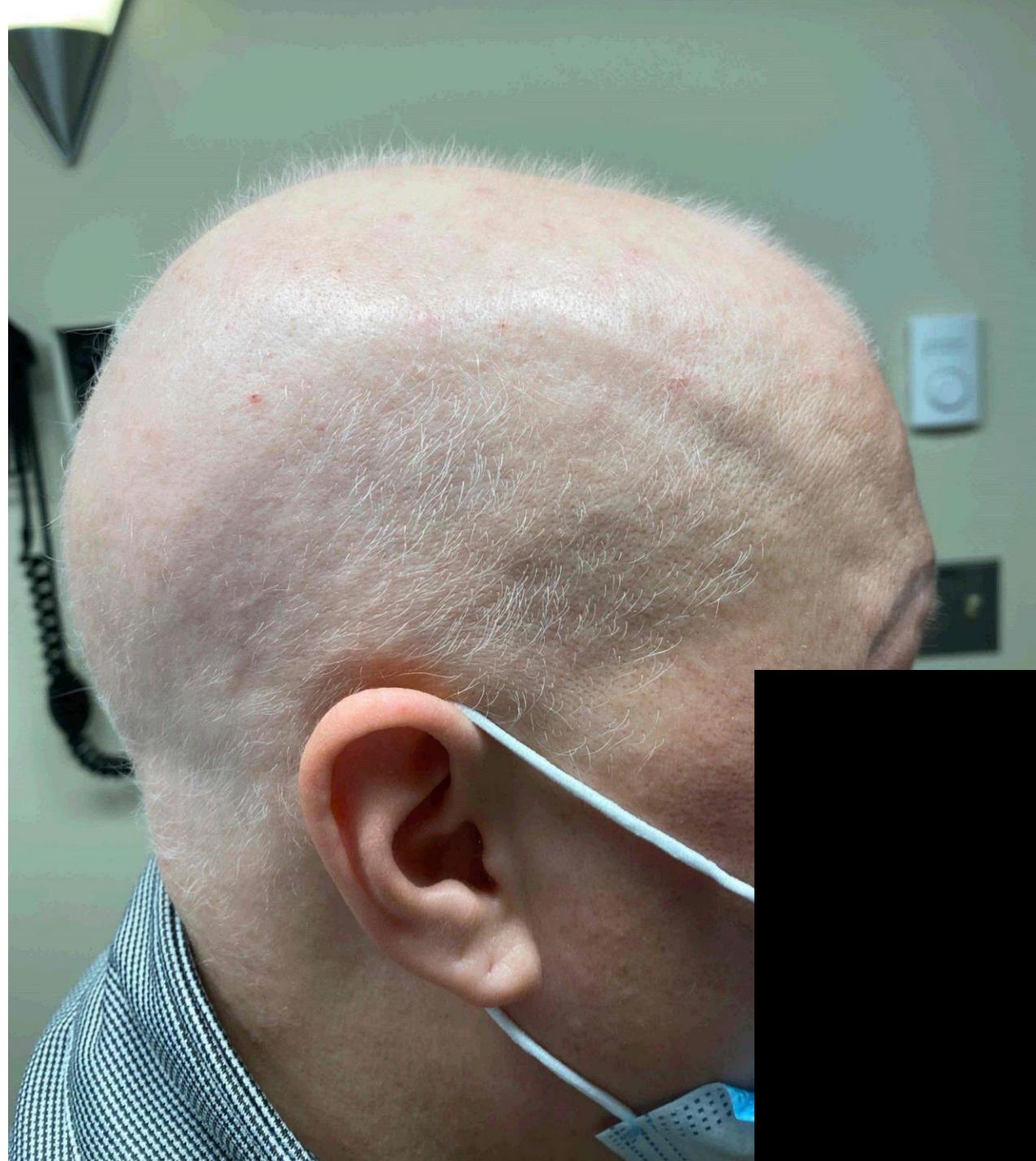
Baricitinib 4mg QD





- Woman in her 50s
- Risk related to VTE, MACE, cancer
 - Clot hx? **YES, provoked DVT years ago, on coumadin**
 - Heart attack or stroke? **NO**
 - Active malignancy? Cancer history/up to date on screening? **Early stage breast cancer, considered cured, up to data on screening**

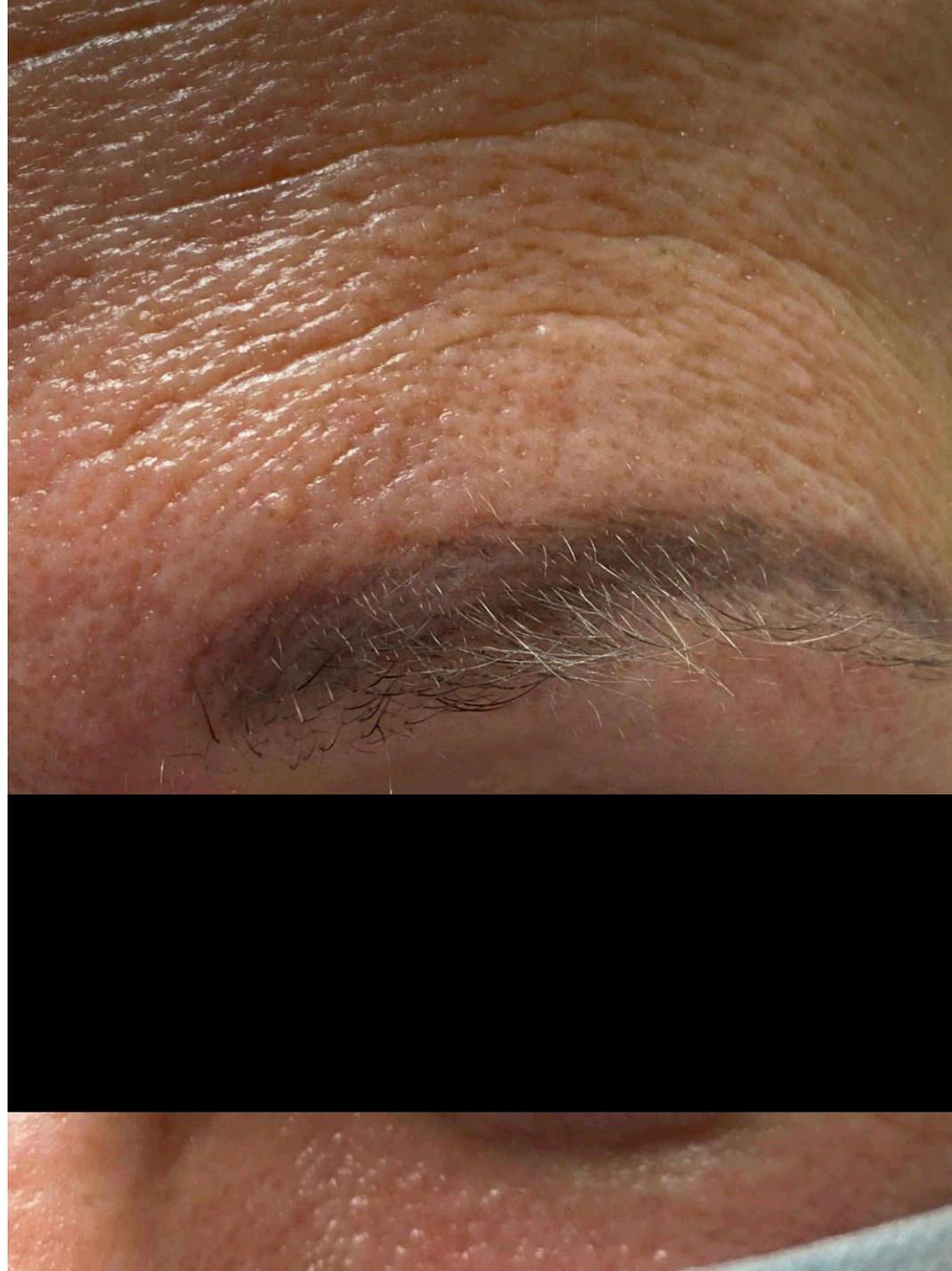
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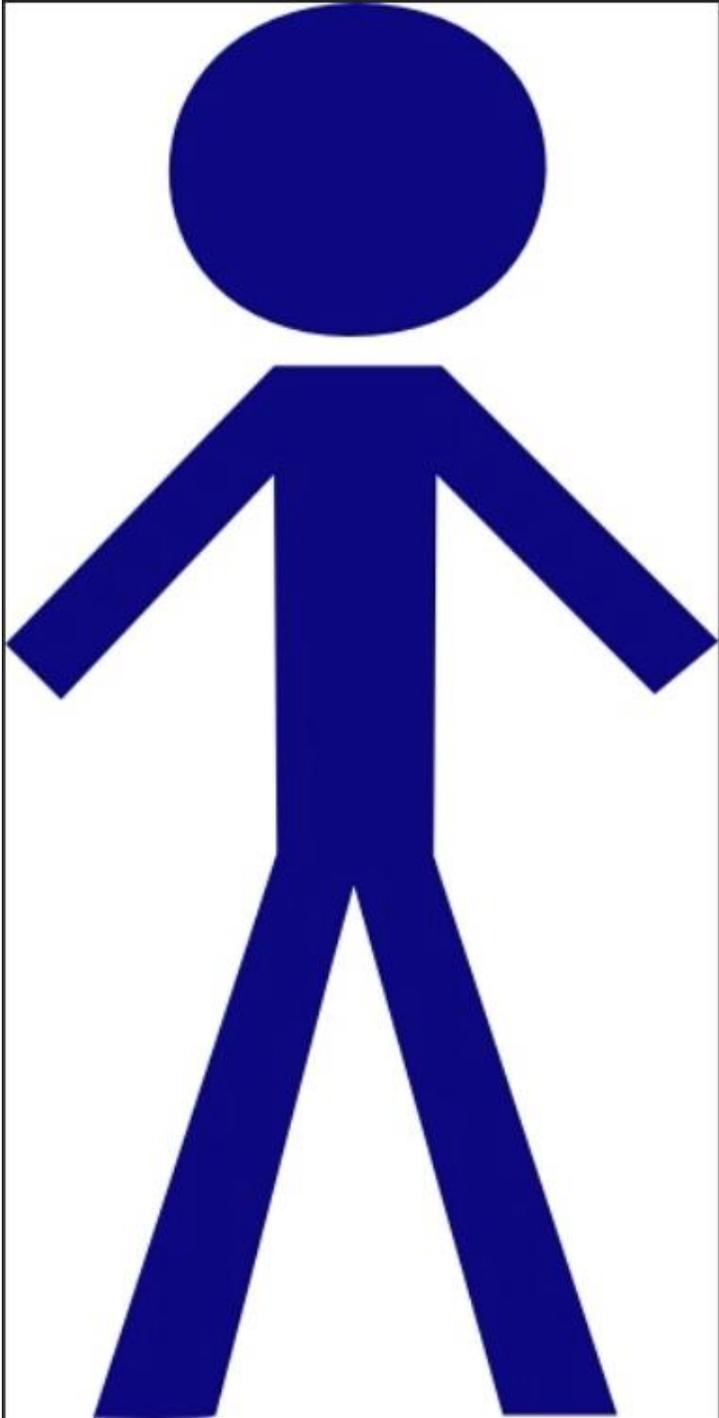
Baricitinib 4mg QD
3 months





Baricitinib 4mg QD
1 year





JAKi Contraindicated?

- Risk related to VTE, MACE, cancer
 - Clot hx? **Hx unprovoked clot, not on anticoagulation**
 - Heart attack or stroke? **With non-controlled ongoing risk factors**
 - Active malignancy? Cancer history/up to date on screening? **Active cancer or cancer with high risk of recurrence**

Case 4





- 48 y/o M
 - Baseline lipids wnl
 - Nurse notes 1 month f/u labs: LDL 160, remaining normal
- Plan?

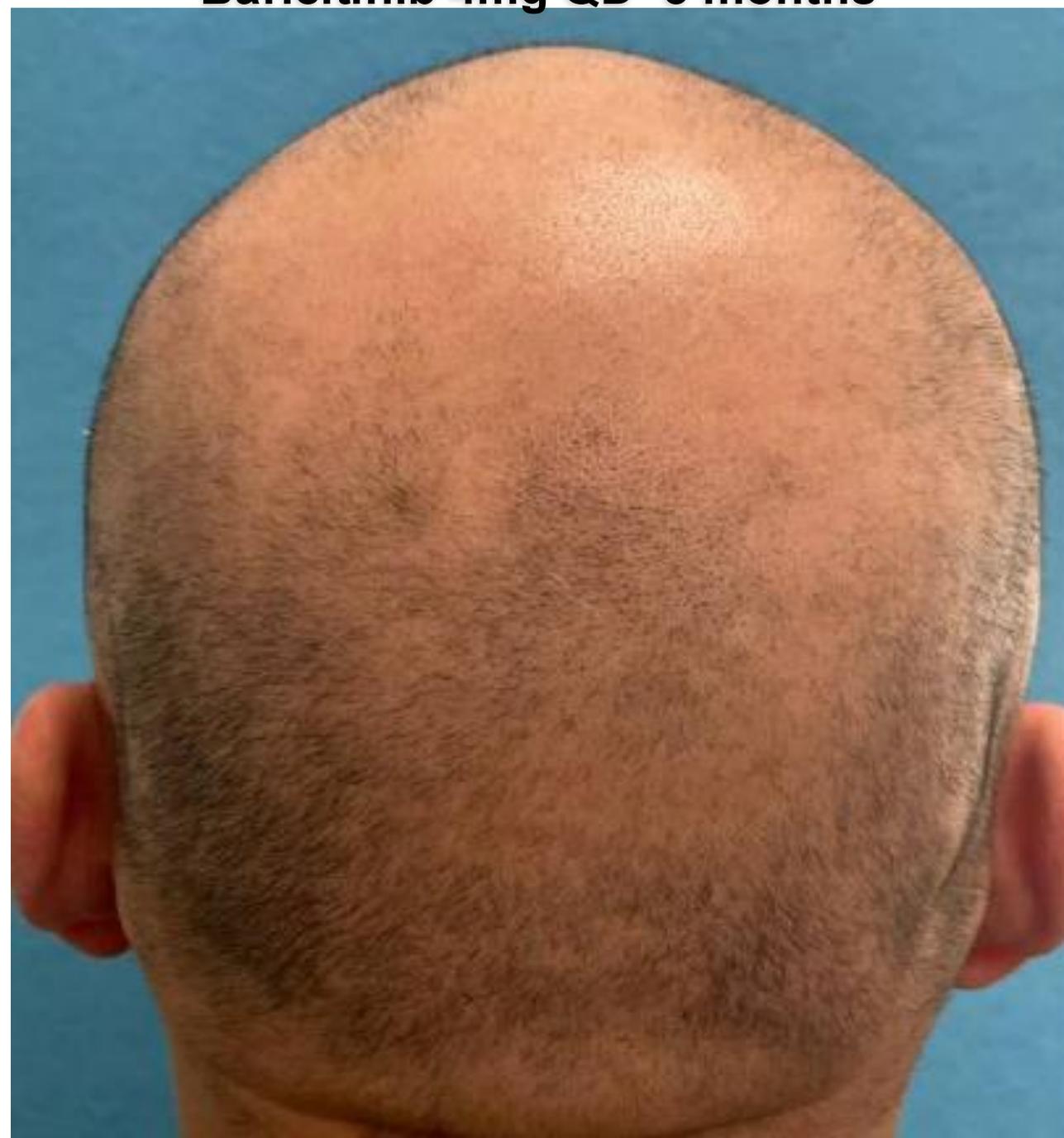


- 48 y/o M
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- Plan? **Not fasting**

Baricitinib 4mg QD
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Baricitinib 4mg QD 3 months

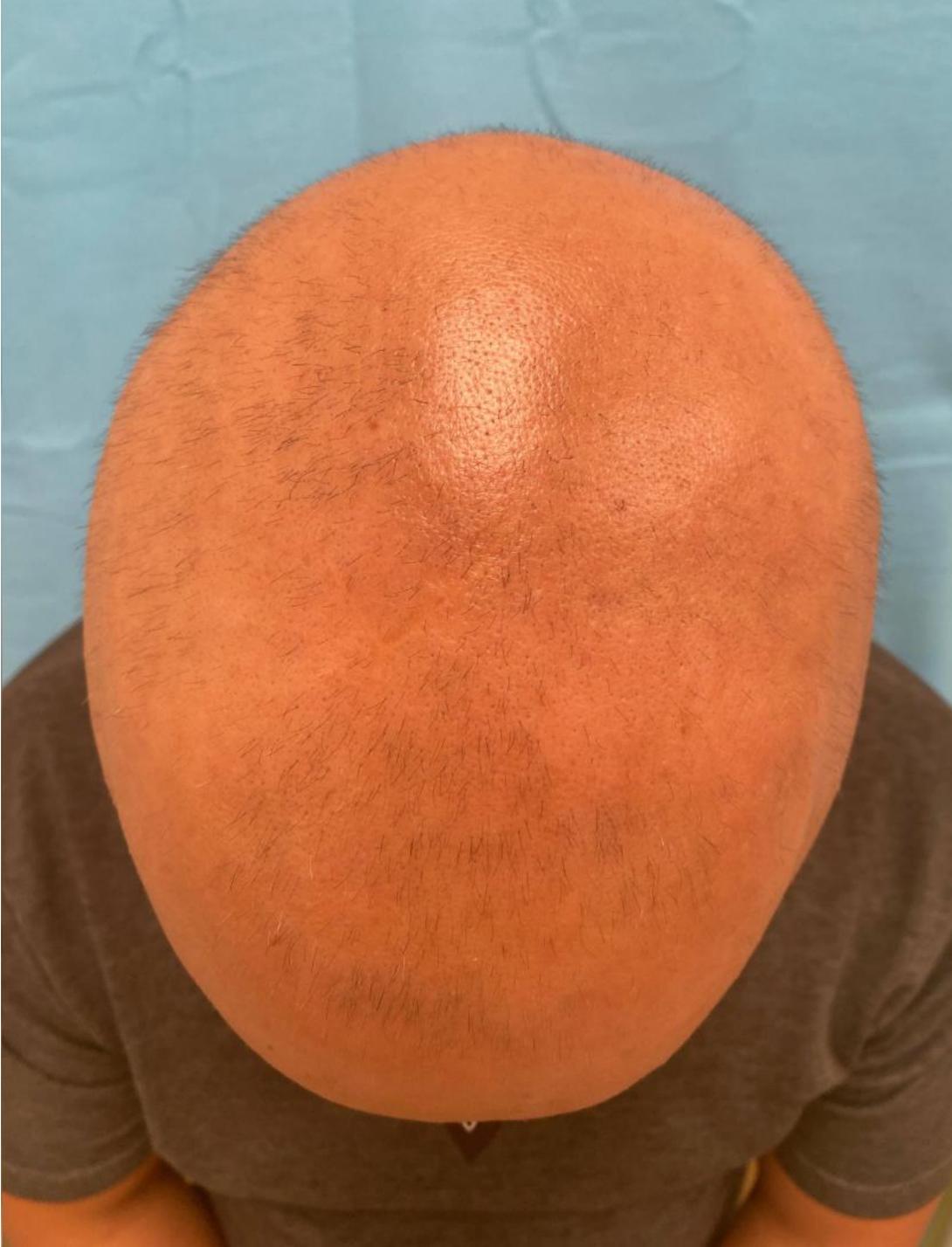


**Baricitinib 4mg QD
3 months**





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- Plan?



- 48 y/o M
 - Baseline lipids wnl
 - Nurse notes 1 month f/u labs: LDL 160, remaining normal
- Plan? **Fasting**



- 48 y/o M
 - Baseline lipids elevated with LDL 210 fasting
 - Plan?



- 48 y/o M
 - Baseline lipids elevated with TG 300 fasting
 - Plan?

Case 5





Alopecia Areata Scale (AASc):

A multidimensional tool for assessing severity

Primary Criterion



MILD
≤20% scalp hair loss



MODERATE
21%-49% scalp hair loss



SEVERE
50%-100% scalp hair loss

Examples of Severity of Scalp Hair Loss²

Secondary Criteria

- Noticeable involvement of eyebrows or eyelashes
- Negative impact on psychosocial functioning resulting from AA
- Inadequate response after 6 months of treatment
- Diffuse (multifocal) positive hair pull test consistent with rapidly progressing AA

If **any** secondary criteria are present, **increase** severity rating by **one level**.

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- 16 y/o M
 - Nurse notes 3 month f/u:
Calling with acne flare
 - Plan?

Baricitinib 4mg QD

■

Characterization of acne associated with upadacitinib treatment in patients with moderate-to-severe atopic dermatitis: A post hoc integrated analysis of 3 phase 3 randomized, double-blind, placebo-controlled trials



Pedro Mendes-Bastos, MD,^a Barry Ladizinski, MD, MPH, MBA,^b Emma Guttman-Yassky, MD, PhD,^c Ping Jiang, MS,^b John Liu, MD,^b Vimal H. Prajapati, MD,^{d,e,f,g,h} Eric L. Simpson, MD,ⁱ Namita Vigna, PhD,^b Henrique D. Teixeira, PhD,^b and Sebastien Barbarot, MD, PhD^j

- 10% of patients on 15 mg daily, 15% of those on 30 mg daily

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- 10% of patients on 15 mg daily, 15% of those on 30 mg daily
- No QOL difference in those who developed acne
- 45% required no treatment

Our Experience: JAKne

- Typically exacerbation of pre-existing disease
- Ok to use oral retinoids concomitantly





Key Practice Take Aways

- Patients with more severe disease need higher dose
- For patients with alopecia totalis or universalis, may take a year for response
- JAK inhibitors should be **standard of care** in patients with alopecia areata who desire treatment

